NeuroPace® Remote Monitor Manual

℞ Only

FCC Information

The following is communications regulation information on the model RNS-300M neurostimulator and model W-02 wand.

Neurostimulator FCC ID: WBWRF300
Wand FCC ID: WBW5200 or WBW902

All components comply with Part 15 of the FCC Rules. Operation is subject to the following 2 conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to these components not expressly approved by NeuroPace, Inc. could void the FCC Certification, and negate your authority to operate them.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Electromagnetic Emissions and Immunity and Wireless Technology

Medical Electrical Equipment needs special precautions regarding EMI and the following precautions should be taken before use.

The remote monitor may cause radio interference or may disrupt the operation of nearby equipment. The remote monitor may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements. It may be necessary to take mitigation measures, such as re-orienting or relocating the remote monitor or shielding its location.

The remote monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the remote monitor should be observed to verify normal operation in the configuration in which it will be used.

Portable and mobile RF communications equipment can affect the remote monitor.

Refer to ***Electromagnetic Emissions and Immunity*** for more information.

Table of Contents

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

Symbol	Meaning
⚠	Caution
(MR)	MR Unsafe
R_X Only	Prescription Only
Use	Temperature limits during use
Storage	Temperature limits during storage or transport
◼	Manufacturer
SN	Serial number
🧍	Type BF applied part
▢	Class II electrical protection
5 V, 0.5 A	Direct current (DC) 5 V (volts), 0.5 A (amperes)
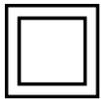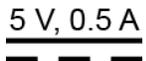
IP22 Ingress protection ratings: Level 2 for solid objects, which means testing confirms the device enclosure prevents ingress (entry) of items greater than 12.5 mm (~1/2 inch), such as fingers or similar objects; Level 2 for liquids, which means testing confirms vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.
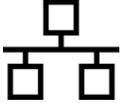
Ethernet Connection (Network Connection)

Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

1.   About the RNS® System

Indications for Use

The RNS® System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than 2 epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures (motor partial seizures, complex partial seizures and / or secondarily generalized seizures). The RNS® System has demonstrated safety and effectiveness in patients who average 3 or more disabling seizures per month over the three most recent months (with no month with fewer than two seizures), and has not been evaluated in patients with less frequent seizures.

Purpose of Your Remote Monitor

The NeuroPace® Remote Monitor (model DTR-300) is designed for use with the RNS® Neurostimulator (model RNS-300M).

A remote monitor lets you collect data from the neurostimulator, and send the data to your doctor. The remote monitor consists of a special software program installed on a laptop computer, a wand and telephone accessories.

After connecting the hand-held wand to the laptop, data in the neurostimulator are collected by placing the wand over the neurostimulator. The wand uses Radio Frequency (RF) communication to collect the data. Data are stored in the laptop and then sent to a secure database over a phone line. The database is called the PDMS (Patient Data Management System) and your doctor can access your data. Your doctor will review the data and use the results to adjust the neurostimulator settings during future office visits.

Important Information

Please see your RNS® System Patient manual for additional information regarding the RNS® System and treatment.

You must be willing to collect data from the neurostimulator, and then send the data to the PDMS database as directed by your doctor. NeuroPace recommends you collect data from the neurostimulator at least once a day and send data to the PDMS database at least once a week.

2. Parts of the NeuroPace® Remote Monitor

Make sure you have all the parts described below. Contact NeuroPace Customer Support if any parts are missing. See the back page of this manual for contact information.

The Remote Monitor Software on Laptop Computer

The remote monitor software program is already installed on the laptop computer. It stores data collected by the wand, and then sends it to the secure PDMS database over a phone line.

The laptop computer you receive may not be the same model shown here. The location of the connections may also differ from the model shown here.

Wand

The Wand plugs into the laptop computer and is applied to the patient (an applied part). You hold it over the neurostimulator to collect data from the neurostimulator and store it in the laptop computer. The wand collects data through Radio Frequency (RF) communication.

Power Cord

The power cord powers the laptop computer and charges its battery. The laptop comes with battery installed, but not fully charged. When the battery is charged, disconnect the power cord before using the wand.

The power cord may come as 1 or 2 pieces, depending on the laptop computer model you receive.

Phone Accessories

The phone accessories let you connect the laptop computer to your phone wall jack. A phone cord is included along with a splitter that converts 1 phone wall jack into 2 separate jacks.

Carrying Case

The carrying case is for storing your remote monitor parts when not in use.

3. Warnings and Cautions

WARNINGS:

Medical Procedures

DO NOT have any of the following procedures before making sure the person administering the procedure knows that you have the RNS® System implanted and they have consulted with the doctor who is monitoring your use of the RNS® System:
- Computerized Tomography (CT or CAT) scans.
- Radiation therapy (such as cobalt 60 or gamma radiation to treat cancer).
- Lithotripsy (shock waves to break up hard masses, such as kidney stones).
- Electrolysis (electrical current to remove unwanted hair).

The energy used in these procedures may damage the RNS® System. This could result in stimulation not being delivered, additional surgery to remove or replace parts of the RNS® System, serious injury, or death.

In addition, Computerized Tomography (CT or CAT) scans should be performed only under the following conditions:

- The neurostimulator should be turned off prior to the procedure if possible. This should be done by your doctor or someone who is authorized to adjust the settings using the NeuroPace® Programmer.

- The scan should be taken at the lowest X-ray beam level possible.

- Avoid directing the beam at or near the implant site for more than a few seconds.

- Emergency services need to be available in the event you have a serious side effect. This is especially important if the scan area includes the implant site.

- The neurostimulator should be turned back on after the procedure.

Lithotripsy and Electrolysis should not be performed on the head or neck.

Contact your doctor as soon as possible if you have questions or suspect your RNS® System is not working properly after any medical procedure.

Interaction with Implanted Cardiac Devices

Possible effects of RNS® System interaction with an implanted cardiac device (such as pacemakers or defibrillators) include the following:

- o Defibrillation therapy from an implanted defibrillator may damage the RNS® System.

- o The electrical pulses from the RNS® System may interact with the sensing operation from a cardiac device and could result in an inappropriate response of the cardiac device and vice versa.

Adverse Tissue Reaction

Allergic reaction to the RNS® System materials and / or leads implanted is possible.

Chronic Tissue Stimulation

The effects of long-term brain stimulation are not completely known and may present some risks to the patient.

Erosion

Skin erosion may occur on and/or around the neurostimulator and/or lead implant site, particularly in the case of protrusion of the implanted RNS® System products above the surface of the skull.

Lead Migration

The implanted lead(s) may migrate from their desired implant location. Lead migration can result in changes in detections and stimulation effectiveness, and may require additional surgical procedures to modify the lead location.

Pregnant Women

The safety and effectiveness of the RNS® System has not been studied in pregnant women.

RNS® System Failure

As with any electronic device, the RNS® System may malfunction (not work). Potential causes include battery malfunctions, an electrical short, open circuits, lead fractures, lead insulation failures, or damage as a result of head trauma. These malfunctions are unpredictable, and may result in too little stimulation or no stimulation. A lead failure may result in the lead needing to be removed or repositioned, which would require surgery. A malfunctioning neurostimulator may need to be replaced, which would require surgery. Although the device is designed to turn off if overstimulation or excess current occurs, there is a possibility that product failure could result in brain tissue damage.

Case Damage

If the neurostimulator case is ruptured or pierced due to outside forces, severe brain tissue damage could result from exposure to the battery chemicals.

Electrical Shock

To avoid electrical shock (as with any electronic device such as a laptop computer):

- **DO NOT** use the wand or laptop when you are wet.
- **DO NOT** apply water or liquids directly to the wand or laptop.
- **DO NOT** modify the power cord that came with your remote monitor in any way. If your remote monitor came with a 3-pronged plug, connect it to an outlet that accepts that type of plug.
- **DO NOT** use the wand or laptop during an electrical storm.
- **DO NOT** clean the wand or laptop with any cleaning liquids or aerosols. Wipe the outside of the wand and laptop with a clean cloth, dampened with water and wrung out. Make sure to disconnect the laptop from the electrical outlet before cleaning.
- **DO NOT** use the wand or laptop if you think they appear to be damaged or are not working properly. **DO NOT** attempt to repair the wand or laptop. Contact NeuroPace Customer Support for assistance.
- **DO NOT** attempt to modify or repair the wand or laptop. Contact NeuroPace Customer Support for assistance.

Not following these instructions may cause an electrical shock that may result in serious injury or death, and may damage the wand or laptop.

NeuroPace Components

Use of accessories, transducers, and cables other than those provided by NeuroPace could result in increased electromagnetic emissions or decreased electromagnetic immunity of the RNS® System and result in improper operation. Do not plug the wand into equipment other than the remote monitor because it could damage the wand. Do not use a USB cable extension from the remote monitor to the wand.

Portable and Mobile Radio Frequency (RF) Communications Equipment

Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the RNS® System, including cables. Otherwise, degradation of the performance of the RNS® System could result.

NeuroPace® Equipment Placement

Use of NeuroPace® equipment (for example, remote monitor or programmer) adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary the NeuroPace® equipment and other equipment should be observed to verify that they are operating normally.

Electromagnetic Interference (EMI)

Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Sources of strong electromagnetic interference can result in the following effects:

- **Serious injury or death** - It is possible for the interference sources to couple enough energy into a neurostimulator system to damage brain tissue.

- **System damage** - resulting in a loss or change in symptom control and requiring reoperation.

- **Operational changes to the neurostimulator** - causing stimulation to turn on or off, or resetting or reprogramming the neurostimulator resulting in a return of symptoms.

- **Unexpected changes in stimulation** - causing a momentary increase in stimulation which may be felt.

You should exercise caution to avoid devices which generate a strong electric or magnetic field. Refer to *Electromagnetic Emissions and Immunity* for more information.

Radio Frequency Identification (RFID) Interference

RFID scanners can produce signals that appear as brain activity to the neurostimulator. Such signals could cause the neurostimulator to deliver stimulation. Potential sources of RFID may occur in a health care environment, retail stores, public libraries, airports and business environments.

Refer to ***Electromagnetic Emissions and Immunity*** for more information.

Airport Security and Other Surveillance Systems

Tell people working with security and theft systems that you have the RNS® System implanted and show your medical implant identification card. Walk through the center of security screening units without stopping, when possible, and exit the area of the screening device as soon as possible. Leave the security area as soon as practical. Security screening devices (such as theft detectors and airport security screening devices) may be found at retail stores, public libraries and airports. Such devices use technology that can cause or temporarily disrupt stimulation while you are being scanned. For more information, contact your local airport security office or TSA (Transportation Safety Administration).

Laptop Overheating

DO NOT cover or enclose the laptop with anything that could restrict airflow through the vents and not allow heat to disperse. All laptop computers generate a moderate amount of heat when they are turned on. Restricting the airflow can damage the laptop or cause a fire.

Wand Placement

DO NOT use (position) the wand over any other medical device. This includes other implanted devices such as a pacemaker or defibrillator, as well as devices that are used outside the body, such as a CPAP machine. Not following these instructions may momentarily interfere with the operation of other medical devices.

Cables

Keep children from playing with the laptop power cord and wand cable, which can pose a risk of strangulation. To prevent damage to cables or the risk of electric shock, prevent pets, pests and children from chewing on cables.

CAUTIONS:

Medical Procedures and Dental Work

Before all medical procedures tell the person administering the procedure that you have the RNS® System implanted. All medical procedures and dental work should be performed with caution. Contact your doctor as soon as possible if you have questions or suspect your RNS® System is not working properly after a medical procedure.

Diagnostic x-rays and diagnostic ultrasounds may be performed without affecting the RNS® System.

Applying Pressure on the Neurostimulator and Leads

DO NOT press on or play with the implanted neurostimulator or leads. This may damage the neurostimulator or leads and result in stimulation not being delivered until they are surgically repaired or replaced.

Magnet

DO NOT drop the magnet onto any hard surface. The magnet can shatter into small, sharp pieces that can cut the skin.

Household Magnets and Magnetic Bracelets

DO NOT put items that contain magnets within 4 inches of the neurostimulator. Magnets contained in such products as stereo speakers, AM/FM radios, power tools, cellular, cordless and conventional phones, as well as magnets used therapeutically or worn on the body may interfere with stimulation. Since it is not always obvious if an item contains a magnet, refer to the packaging and instructions that came with the item for more information. You can also call the manufacturer of the item and ask them. Most headsets and earphones available in stores do not interfere with stimulation, but not all have been tested.

Battery Depletion

For continued operation, the neurostimulator needs to be surgically replaced when the battery is depleted. Your doctor will let you know when the neurostimulator needs to be replaced.

Neurostimulator Longevity

High and frequent levels of stimulation reduce neurostimulator battery longevity.

Explantation and EMI considerations

Before all medical procedures tell the person administering the procedure that you have the RNS® System implanted if any system components (neurostimulator, leads, leads fragments or cranial prosthesis) remain implanted after you stop using the RNS® System. You could still experience side effects from EMI if any system parts remain implanted. These effects may result in stimulation of the brain tissue and tissue damage resulting in serious injury or death.

Refer to *Electromagnetic Emissions and Immunity* for more information.

Lead replacement and abandoned leads

The long-term safety associated with leads left in place without use, replacement of leads, and lead removal is unknown.

Other Active Implanted Medical Devices

RNS® System interactions with other active implantable medical devices (such as pacemakers, defibrillators, implanted spinal cord and peripheral nerve stimulators, cochlear implants, and vagus nerve stimulators) are not known. Contact your doctor to discuss your situation or to answer questions.

Scuba diving or hyperbaric chambers

DO NOT dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Such pressures could damage the RNS® System.

Patient Population for which safety and efficacy have not been established

The safety and effectiveness of the RNS® System has not been established for:
- o People with generalized epilepsy.
- o People with a seizure focus that cannot be adequately localized.
- o Pregnant women.
- o People under the age of 18.
- o People with simple partial sensory seizures only.
- o People with less than three seizures a month on average.
- o People who have more than two epileptic foci.
- o People who have not failed two antiepileptic drugs.

Safety and Effectiveness beyond 24 months

The safety and effectiveness of the RNS® System beyond 24 months is unknown.

Remote Monitor Laptop

DO NOT use the laptop for any other purpose except as instructed in this manual. The laptop is designed to operate only as part of the remote monitor. **DO NOT** make any changes or adjustments to the laptop hardware or software. This includes attaching external devices like a mouse, or inserting CDs or DVDs into the drive. Any changes you make that are not part of the instructions in this manual may damage the remote monitor and may not allow you to send data to the PDMS database.

Data Collection

You should collect data from the neurostimulator, and send data to the PDMS database, as directed by your doctor. NeuroPace recommends you collect data from the neurostimulator at least once a day and send data to the PDMS database at least once a week. By sending your data on a regular basis, your doctor will be able to identify problems and make adjustments. Your doctor will also be able to determine when battery power is getting low. If you do not collect and send data as directed, your doctor may not be able to review your data and make adjustments on a timely basis.

If you are having seizures more frequently or with greater severity, talk with your doctor as soon as possible. Your doctor may ask you to collect and send data to the PDMS database on a more frequent basis until adjustments can be made to the neurostimulator settings.

Talk to your doctor about what you should do if you are unable to collect data from your neurostimulator or send data to the PDMS database as directed.

Wand Signal Test

DO NOT test the wand signal for more than 10 minutes a day. Testing the wand signal for more than 10 minutes a day may cause the neurostimulator battery to drain more quickly than expected.

Operating Temperatures

DO NOT use the wand or laptop in temperatures above or below the recommended operating range (32°F - 95°F). The wand or laptop may not operate properly at temperatures below 32°F or above 95°F. These devices may also become warm during normal operation. **DO NOT** use them when the room temperature is above 95°F to avoid discomfort.

Remote Monitor Setup

DO NOT set up the remote monitor where people can trip over the cords. The cords may be tripping hazards, especially for small children and pets. Tripping over the cords may damage the remote monitor parts, and may result in bodily injury. **DO NOT** rest anything on the power cord. **DO NOT** plug the wand into equipment other than the remote monitor because it could damage the wand. **DO NOT** use a USB cable extension from the remote monitor to the wand.

DO NOT move the remote monitor to another location without first disconnecting the parts and storing them in the carrying case. Disconnect the wand and all cords from the laptop. You may damage the parts if you do not disconnect them before moving them.

Remote Monitor Phone Line Use

You cannot make an outgoing call <u>and</u> send data at the same time, using the same phone number. If you need to make an emergency call while the remote monitor is sending data, disconnect the phone cord from the laptop. This will suspend data transmission so you can make the call. Any unsent data will be included with the data you send the next time.

Analog Phone Line

DO NOT connect your remote monitor laptop to any type of digital phone line such as phone systems used in many hotels and offices, phone service provided by cable companies, and VoIP (voice over internet protocol). The remote monitor must be connected to an analog phone line. Connecting to a digital phone line will damage the laptop and not allow you to send data to the PDMS database. You will still be able to use the remote monitor to collect data from the neurostimulator.

4.   Set up the Remote Monitor

The patient in the home is an intended operator of the remote monitor with wand. Follow the steps below to set up the remote monitor for use. Contact NeuroPace Customer Support if you need assistance to set it up or to report any unexpected events.

Step 1

Find a suitable place to set up the remote monitor. Make sure you review the ***Warnings and Cautions*** on page 4 before choosing a location.

This should be an area:

- o   Away from water, moisture or dampness that can damage the wand and laptop.
- o   Away from extreme temperatures (below 32°F or above 95°F) that can interfere with wand and laptop operation.
- o   Away from small children and pets who can damage the wand and laptop.
- o   Away from large electrical appliances that might be a source of electromagnetic interference (EMI) and interfere with wand and laptop operation.
- o   Close to an analog phone line jack.
- o   Near an electrical outlet that will accept the type of power cord plug that came with your laptop.

You will not be able to confirm that there are no large sources of EMI nearby until you test the wand signal. See ***Test the Wand Signal*** on page 23 for more information.

Determine if the remote monitor will be sharing the same wall jack as your phone. If so, it is recommended that you use the splitter that is provided. This will allow you to connect 2 phone cords (one for the remote monitor and one for your regular phone) to the same wall jack. This way you can keep your regular phone connected at all times.

CAUTION: DO NOT connect your remote monitor laptop to any type of digital phone line such as phone systems used in many hotels and offices, phone service provided by cable companies, and VoIP (voice over internet protocol). The remote monitor must be connected to an analog phone line. Connecting to a digital phone line will damage the laptop and not allow you to send data to the PDMS database. You will still be able to use the remote monitor to collect data from the neurostimulator.

If you are not sure what type of phone line you have, call your phone service provider and ask them.

Step 2

Locate the power connection on the side or back of your laptop. Plug one end of the power cord into the laptop and the other end into an electrical outlet. You may need an outlet that accepts a 3-pronged plug. If your power cord comes as 2 separate pieces, first attach the 2 pieces before connecting the laptop to the outlet.
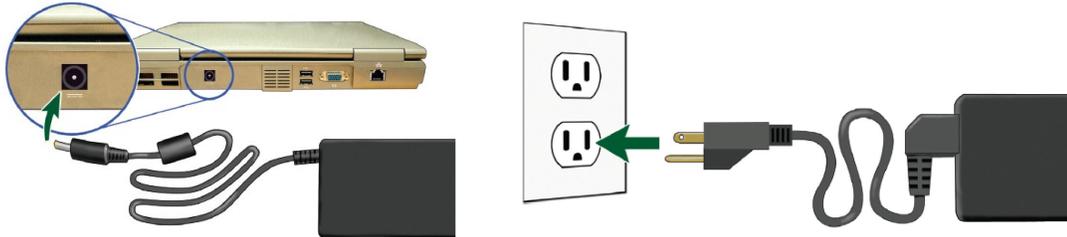
Step 3

*Skip this step if the remote monitor will not share the same wall jack as your regular phone.*

Disconnect your regular phone cord from the wall jack.

Connect the splitter to the phone wall jack.
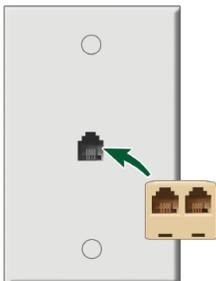
Connect your regular phone cord to the splitter.
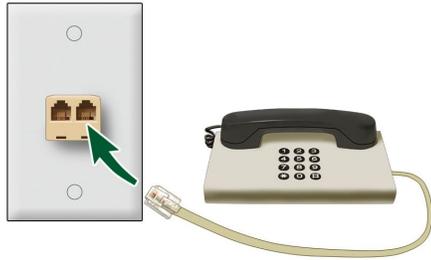
Step 4

Locate the phone connection symbol ( ) on the side or back of your laptop. Take the phone cord (provided) and connect one end to the laptop.
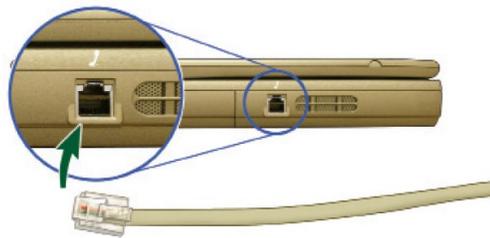
Then connect the other end to the wall jack (or splitter).
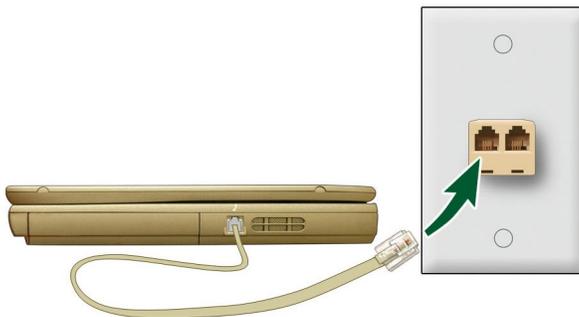
Step 5

Locate the USB connection symbol ( ) on your laptop. Plug the wand cord into the USB port.

Remote monitor setup is now complete. The image below illustrates the connections after the battery is charged and you have removed the power cord, so the remote monitor is ready for use.
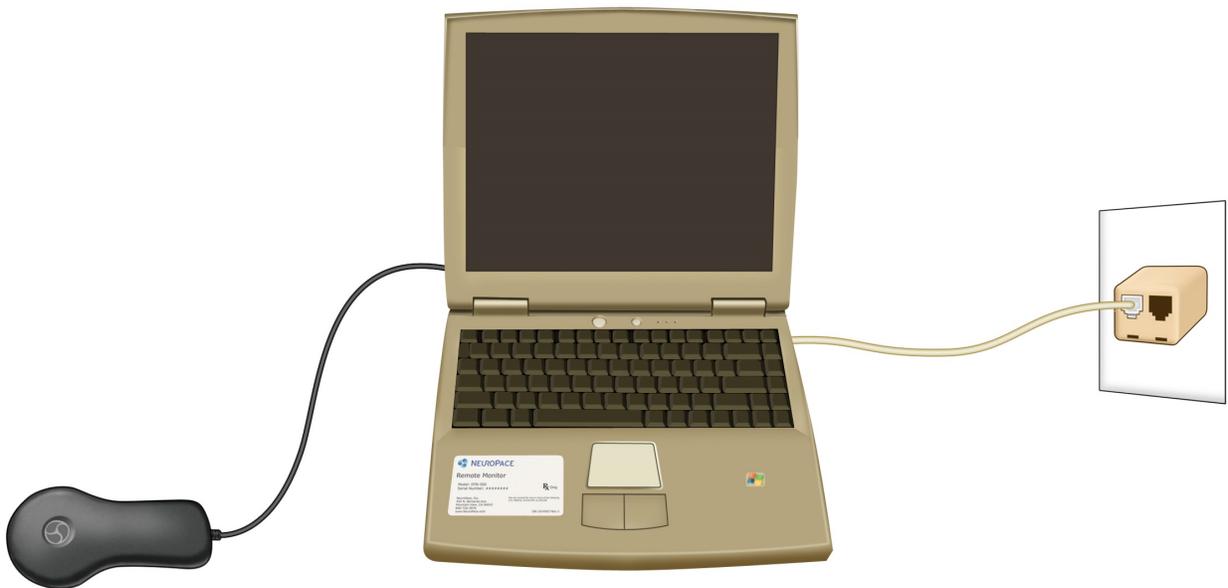
To confirm that the remote monitor is set up correctly, you should:

1) *Test the Wand Signal* (see page 23)
2) *Collect Data from the Neurostimulator* (see page 26)
3) *Send Data to the PDMS Database* (see page 28)

If you are able to complete all three successfully, you have properly set up the remote monitor. If not, see *Troubleshooting* on page 39 for information on how to solve the problem.

5.   Remote Monitor Basics

The main components of the remote monitor are the laptop computer with the special software installed and the wand. You will use the wand to collect data from the neurostimulator, and store it in the laptop computer. The laptop is then used to send the data over an analog phone line to a secure PDMS database that your doctor can access. The remote monitor also lets you test the signal between the wand and neurostimulator to verify you have a strong signal. A software program installed on the laptop controls the use of the remote monitor.

NOTE: Software screens that appear on the laptop and that are described below may not exactly match the screens that will appear on your laptop. This is due to differences in the type of laptop you may receive as part of the RNS® System.

Turn on the Remote Monitor

NOTE:

- o Before turning on the remote monitor, be sure you have completed the section *Set up the Remote Monitor* on page 13.
- o If this is the first time you are using the remote monitor, the laptop battery will not be fully charged until it is plugged into the outlet for about two hours.

Step 1

Open the laptop.
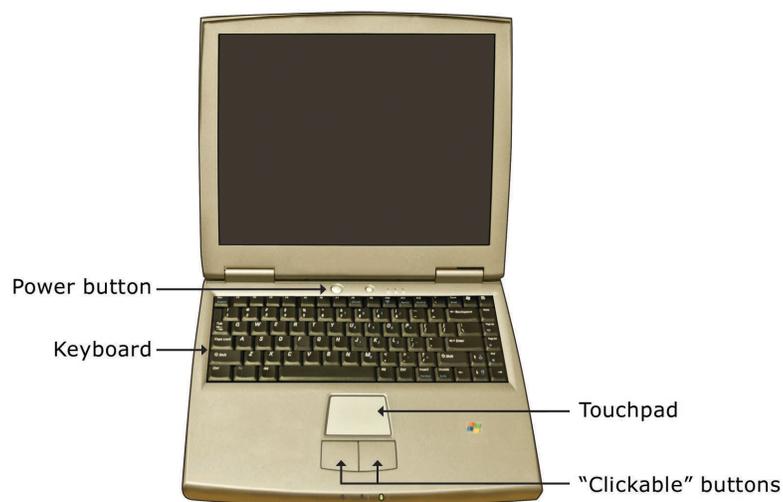
Step 2

Press the power button (⏻) on the laptop to turn it on.
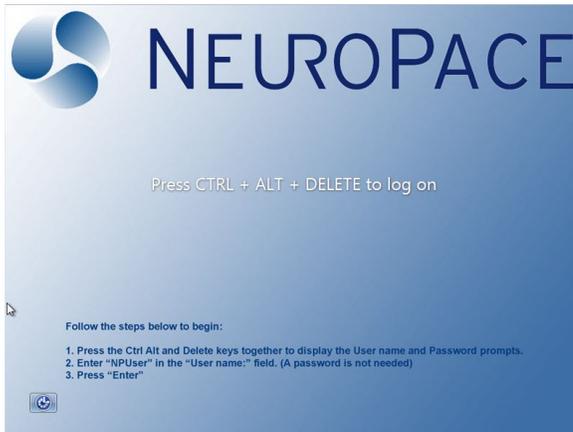
The home screen will appear whenever you turn the laptop on.

NOTE: If the laptop does not turn on, it may not be connected to an electrical outlet, or the laptop battery may be drained.

Laptop Touchpad and Buttons

To use the remote monitor, you will need to know how to move through the screens that will appear on the laptop display. Navigation is controlled with the laptop touchpad and adjacent buttons. The touchpad is located under the laptop keyboard. Below the touchpad are two "clickable" buttons.

The laptop keyboard is used to enter information, like your user name.

Slide your finger on the touchpad to move the cursor (↖) around the laptop screen to a desired location. This is how you move about screens.

The left "clickable" button is used to select an item on the screen once your cursor is in the desired spot. Throughout this manual when the instructions say to "click" use the left clickable button.

*NOTE:* There is no need to connect a mouse to the remote monitor.

Log in to the Remote Monitor

Step 1

Turn on the Remote Monitor (see page 17).

Step 2

Press and hold Ctrl, Alt and Delete on the keyboard. Keep all keys pressed down together until the login screen appears.
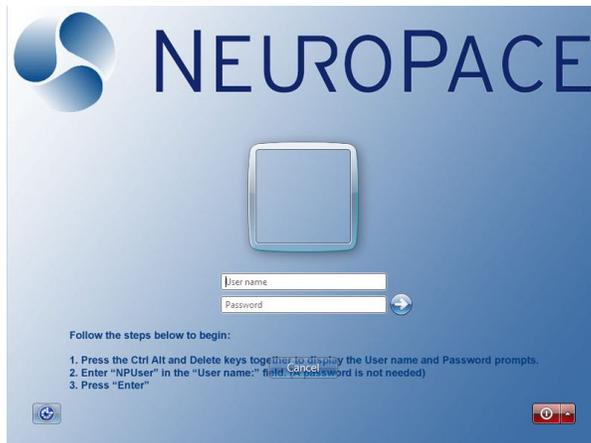

Step 3

If **NPUser** does not appear in the "User name" box, move the cursor over the User name box and click. Then, use the keyboard to enter **NPUser** in the box. This is the User name you will see or enter every time you see this screen.

NOTE: The User name NPUser is not case-sensitive.
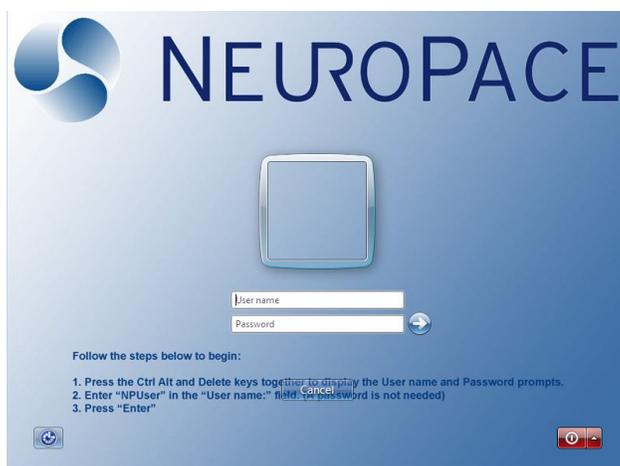
Ignore the bottom "Password" box. You do not need to enter a password in order to continue. Click the arrow button, to the right of the "Password" box, to log in.

The main menu screen will appear when you log in.
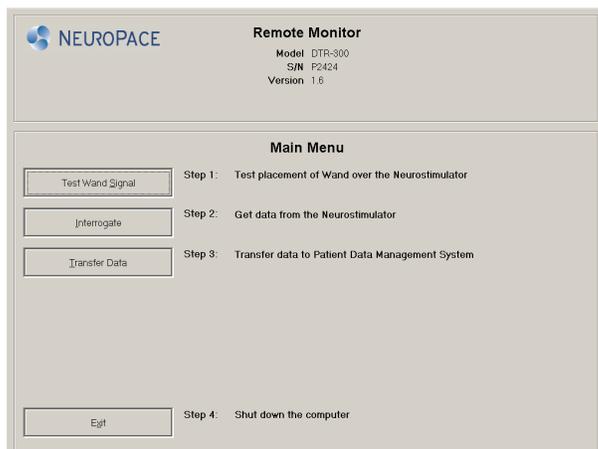
Turn off the Remote Monitor

When you are finished using the remote monitor, be sure to turn it off. This will help conserve laptop battery power and electricity when not in use. The remote monitor laptop does not automatically go into "sleep" mode if you forget to turn it off.

Step 1

Click the **Exit** button on the main menu screen.
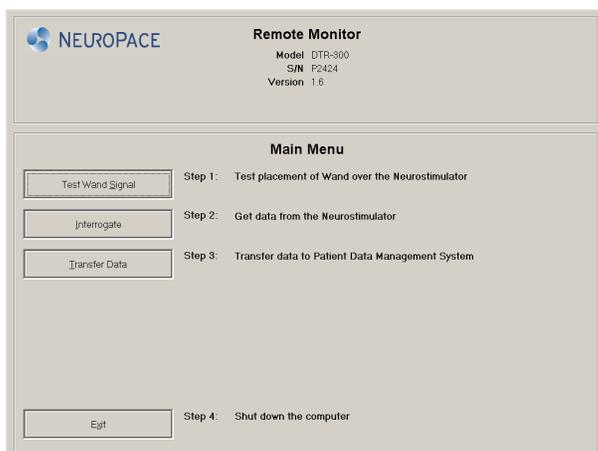
Step 2

Click the **Yes** button to exit the program and turn off the remote monitor.
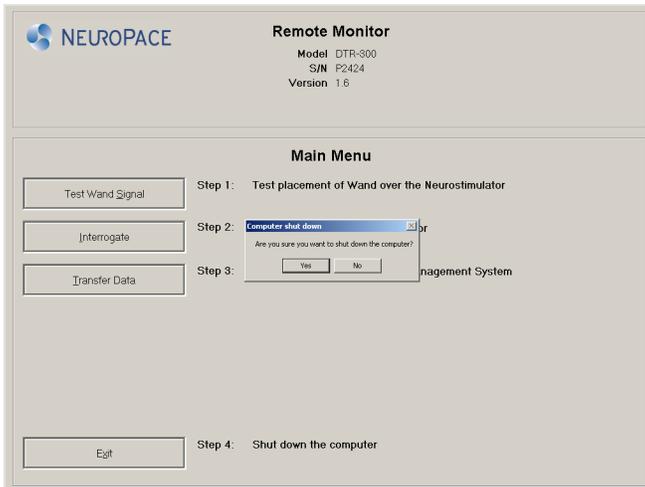
6. Wand Signal Basics

The wand is used to collect data from the neurostimulator and store it in the laptop. Data are collected using Radio Frequency (RF) communication. This collection of data can be affected by Electromagnetic interference (EMI). To help prevent EMI, do not use the wand when the laptop is plugged in to an electrical outlet. Instead, make sure the laptop battery is sufficiently charged and unplug the laptop before using the wand. You should test the wand signal to confirm proper placement of the wand and that there are no large sources of EMI that may affect data collection when:

- o You first set up the remote monitor.
- o You move the remote monitor to a new location.
- o You have problems collecting data.
- o You want to practice your placement of the wand over the neurostimulator to see how it affects signal strength. For best results keep the wand directly over the neurostimulator.

NOTE: Before using the wand, make sure the laptop is sufficiently charged and unplug it from the electrical outlet.

NOTE: Testing the wand signal uses battery power in the neurostimulator. If you test the wand signal for more than 5 minutes at a time, a pop-up window will appear on the screen with a message instructing you to stop.

7. Test the Wand Signal

You should test the wand signal to confirm proper placement of the wand and that there are no large sources of EMI that may affect data collection. Refer to *Electromagnetic Emissions and Immunity* for more information.

Step 1

Log in to the Remote Monitor (see page 19).

Step 2

Place the cupped side of the wand over the neurostimulator and rest the wand on the scalp. It should be no more than about 1 inch away from the center of the neurostimulator. For best results keep the wand directly over the neurostimulator.

Cupped side of wand
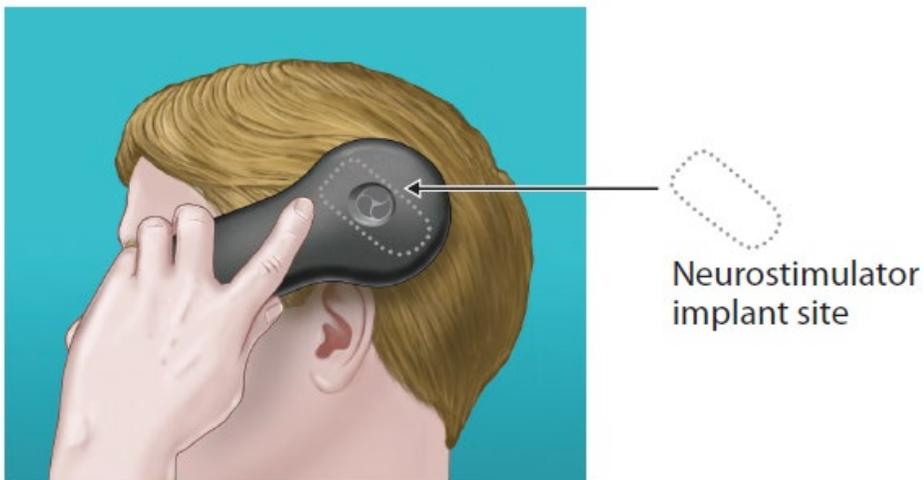
Neurostimulator implant site

Step 3

Click the **Test Wand Signal** button on the main menu screen.
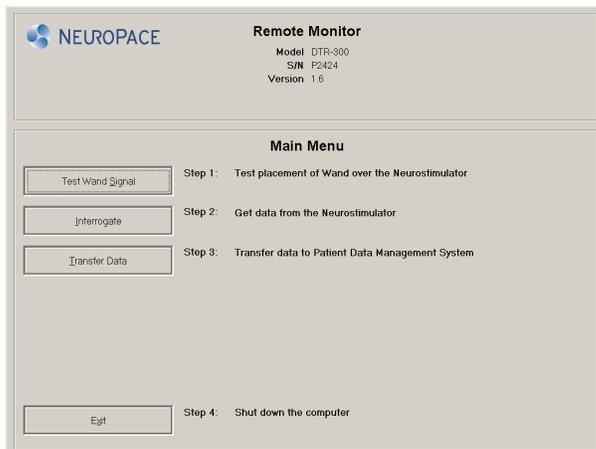
A pop-up window appears on the screen with 2 vertical blue bars. The first bar shows the signal level (the current signal strength between the wand and the neurostimulator). The level bar height will vary as you move the wand closer or further from the neurostimulator. The second bar shows the signal quality (the current signal strength based on how free the signal is from interference).
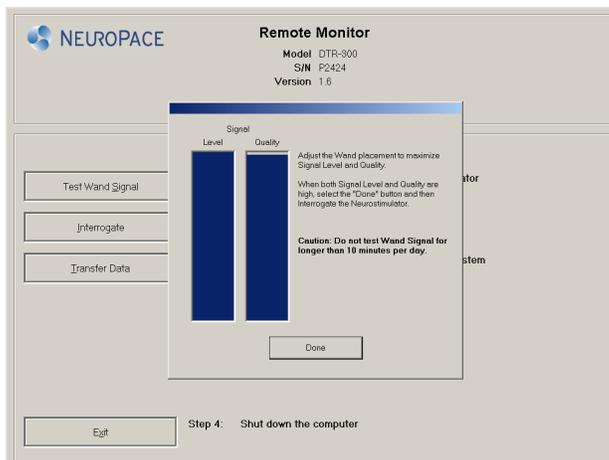
Both bars will range from empty to full, with the height of the bars representing the level and quality of the current signal. Signal level and quality are considered "high" when the bars are at least half full. This will typically allow for data collection to occur without interruption.

Step 4

Move the wand over the neurostimulator until both bars are at least half full. Try to find the spot where signal strength is as close to the maximum level as possible. If you are unable to get the signal quality at least half full you can:

- o Unplug the laptop from the electrical outlet and use battery power.

- o Move the remote monitor to another location.

Repeat these steps until both bars are at least half full.

Step 5

Click **Done** to go back to the main menu screen.

You have successfully set up the remote monitor and wand for data collection. From the main menu screen you can choose to ***Collect Data from the Neurostimulator*** (see page 26) or ***Turn off the Remote Monitor*** (see page 20).

CAUTION: DO NOT test the wand signal for more than 10 minutes a day. Testing the wand signal for more than 10 minutes a day may cause the neurostimulator battery to drain more quickly than expected.

8. Collect Data from the Neurostimulator

When collecting data, you will need to position the wand so that signal strength is at least half full.

Step 1

Log in to the Remote Monitor (see page 19).

Step 2

Click the **Interrogate** button from the main menu screen.
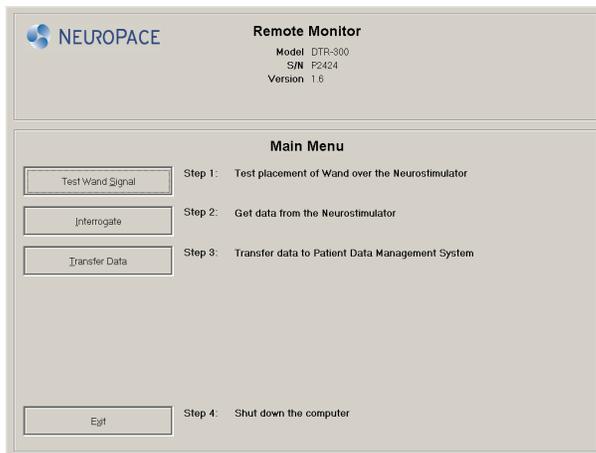
A pop-up window with "**Gathering information**" appears on the screen to let you know that data collection has begun. Data collected from the neurostimulator are stored in the laptop.
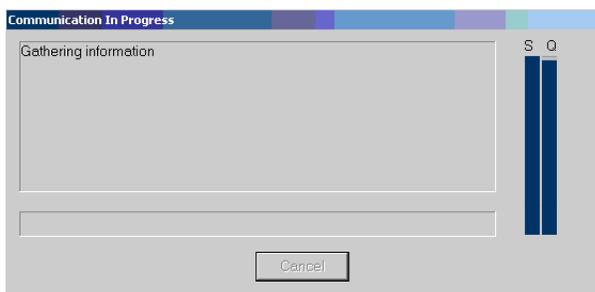
NOTE: The signal strength and signal quality bars that appear when testing the wand signal also appear here. This is to help you find the best wand position for collecting the data.

If you move the wand too far away from the neurostimulator during data collection, the following message may appear: **"Telemetry has been lost. Reposition the Wand over the Neurostimulator and try again."**

Move the wand closer to the neurostimulator until "Gathering information" reappears. This means that data collection has resumed.

If you get another type of error message, follow the instructions on the screen. Then click the **Retry** button. See the *Troubleshooting* (page 39) section for more information on error messages that might appear. If you still need assistance, contact NeuroPace Customer Support.

Step 3

Click the **Return to Main Menu** button to go back to the main menu screen.
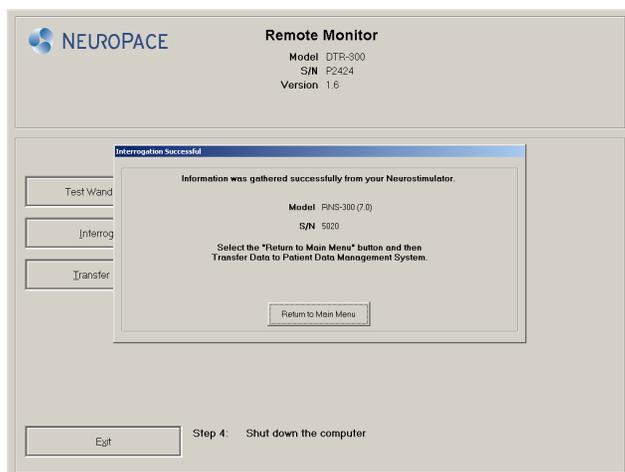
You have successfully collected data from your neurostimulator. From the main menu screen you can choose to *Send Data to the PDMS Database* (see page 28) or *Turn off the Remote Monitor* (see page 20).

9. Send Data to the PDMS Database

You will use your remote monitor to send data stored in the laptop to the secure PDMS database. Data are sent over an analog phone line. The remote monitor must first connect to the PDMS database server before data will be sent. This allows the PDMS database to identify where the data is coming from. If your remote monitor and phone share the same phone line, you cannot make outgoing calls or receive incoming phone calls while you are sending data. Incoming or outgoing calls will interrupt data transmission. Before you begin sending data, make sure your phone is not in use.

CAUTION: You cannot make an outgoing call and send data at the same time over the same phone line. If you need to make an emergency call while the remote monitor is sending data, disconnect the phone cord from the laptop. This will suspend data transmission so you can make the call. Any unsent data will be sent the next time you send data.

If you have "call waiting" on your phone line, you may need to temporarily disable this feature while you are sending data. Call waiting sends a call signal to your phone line that an outside call is waiting for you to pick up the call. When you are sending data, you would not be aware that the call waiting signal is coming through, but the signal may interrupt data transmission. If you have difficulty sending data, you can have the remote monitor automatically disable call waiting whenever data are being sent. Call waiting is then automatically turned back on when data transmission is complete. See *Disable Call Waiting* on page 32.

NOTE: It is not necessary to disable call waiting through your phone company.

Step 1
Log in to the Remote Monitor (see page 19).

Step 2

Click the **Transfer Data** button on the main menu screen.
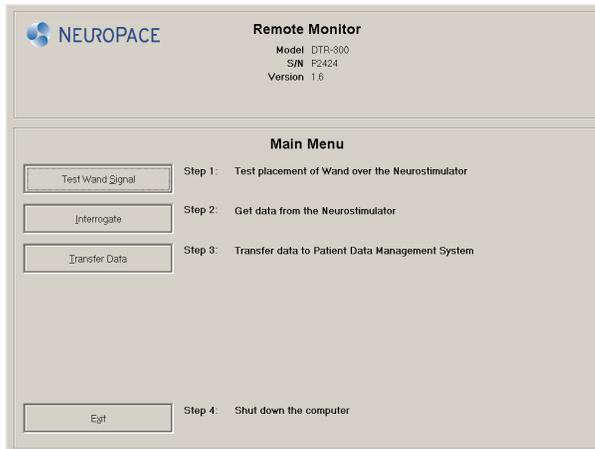
Step 3

Click the **Synchronize** button.
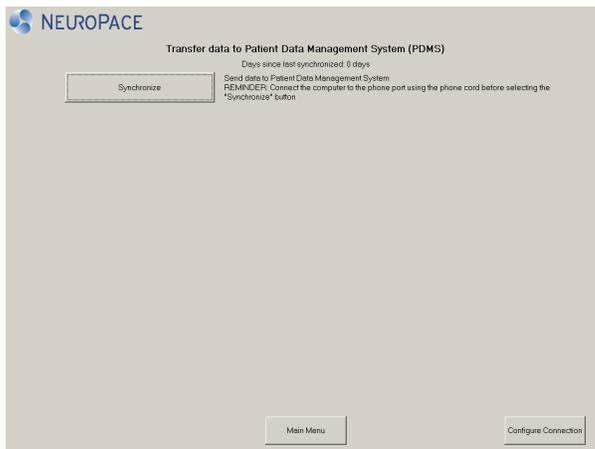
A pop-up window appears on the screen to let you know that the remote monitor is connecting to the PDMS database.
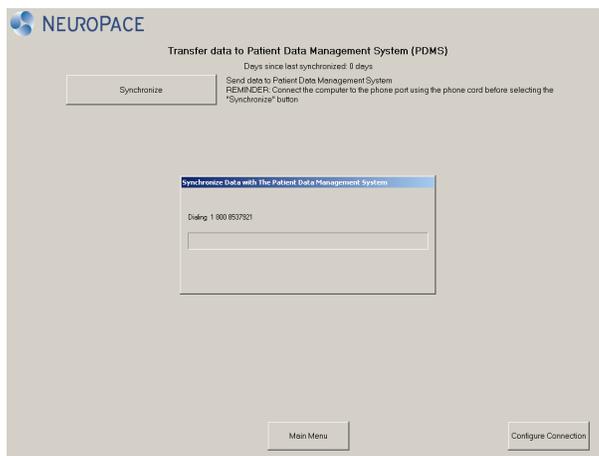
Once connected, data transmission will begin. A second pop-up window shows you the status of data being sent. Allow up to 20 minutes for data to be sent.
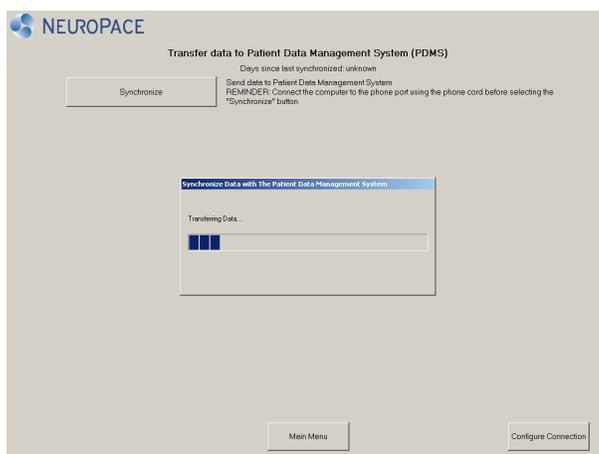
NOTE:

- o If you get an error message, write down the message. You may need to refer to the message when troubleshooting or when contacting NeuroPace Customer Support. Then click the **OK** button.

- o If a pop-up window with a "**Synchronization failed**" message appears, click the **OK** button. See *Troubleshooting* on page 39 for information on how to solve the problem.

- o If data transmission stops or is interrupted, any unsent data will be stored in the laptop. It will be sent to the PDMS database with the next data transmission.

Step 4

Click the **Ok** button on the **Synchronization completed successfully** pop-up window.
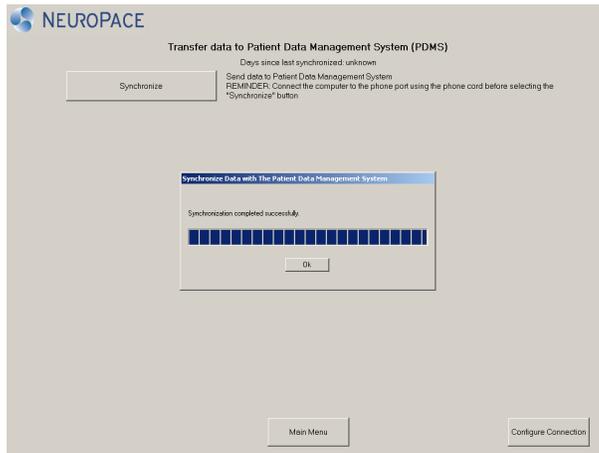
Step 5

Click the **Main Menu** button to go back to the main menu screen.

You have successfully sent data to the PDMS database. From the main menu screen you can choose to *Turn off the Remote Monitor* (see page 20).

10. Disable Call Waiting

The remote monitor sends your data to the secure PDMS database through a toll-free phone number that is programmed into the laptop. The call waiting feature can interrupt data transmission. You can change the remote monitor settings to automatically disable call waiting whenever data are being sent. Call waiting is then automatically turned back on when data has been sent.

If you plan to disable call waiting, you will need to call your current phone service (or service at your current location), and ask them for the code that disables call waiting.

NOTE: You only need to enter and save the code numbers once to have call waiting disabled each time you send data to the PDMS database.

Step 1
Log in to the Remote Monitor (see page 19).

Step 2
Click the **Transfer Data** button on the main menu screen.
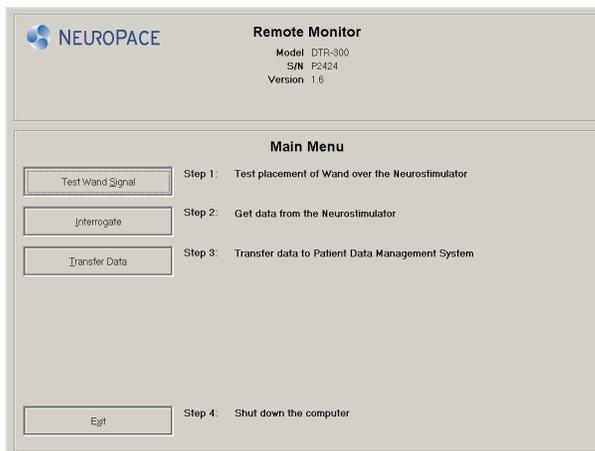
Step 3

Click the **Configure Connection** button.
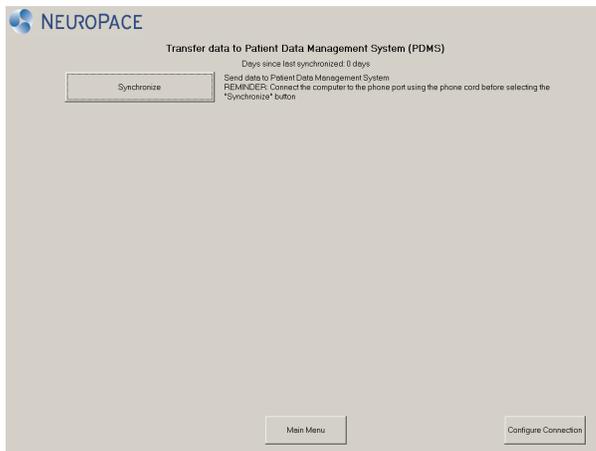
The **Phone and Modem Options** window appears on the screen.
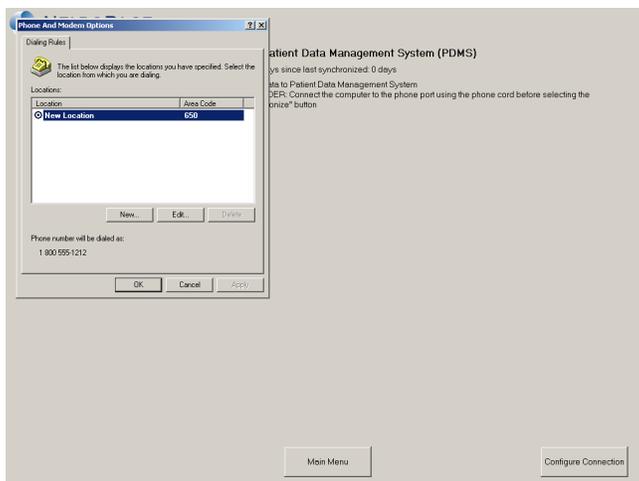
Step 4

Click on **New Location** to activate the **Edit** button.
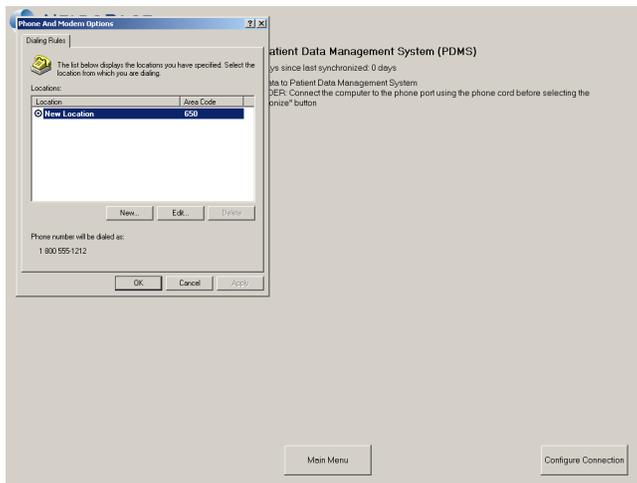
Step 5

Click the **Edit** button.

The **Edit Location** pop-up window appears.

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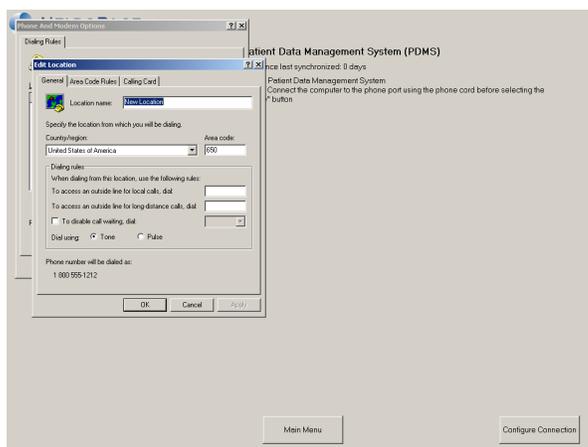
Step 6

Click the box that lets you disable call waiting on the **Edit Location** window.
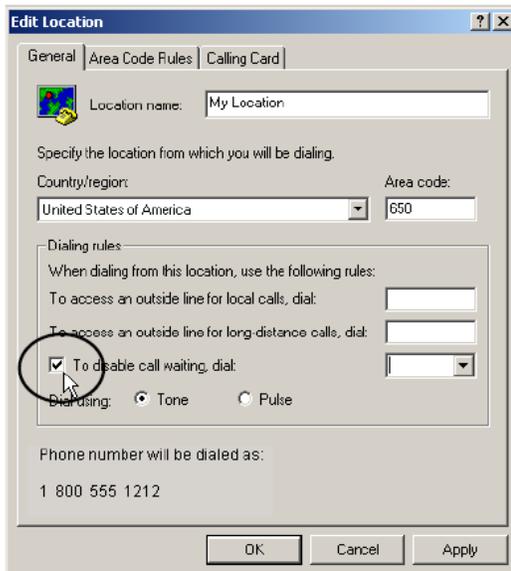
Step 7

Click the down arrow ( ) to the right of the box you just clicked. A drop-down list of code numbers will appear. If you see the code number you obtained from your phone service provider, click it. If it is not listed, enter the number using the keyboard.
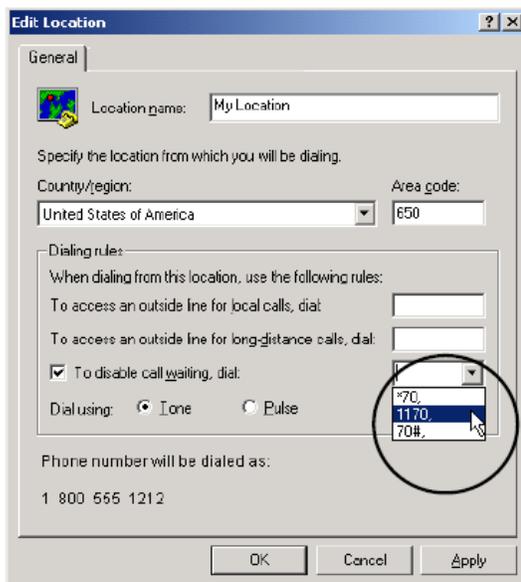
NOTE: The code number you enter and save will be used to disable call waiting every time you send data, until you either change it or delete the code number.

Step 8

Click the **OK** button to save the new setting and return to the **Phone and Modem Options** window. Click the **OK** button to return to the transfer data screen.

NOTE: **DO NOT** change any of the other settings on the edit location screen. Doing so may prevent data from being sent to the PDMS database.

11. Traveling with the Remote Monitor

There are a few things you need to be aware of when traveling. If you plan to take the remote monitor with you, make sure to disassemble the parts and store them in the carrying case.

Airport Security

The laptop can be treated like any other computer when going through airport security.

Traveling for an Extended Period of Time within the U.S.

If you are unable to bring your remote monitor with you, you will not be able to transfer your neurostimulator data as directed. Talk with your doctor in advance to find out what you should do in these situations.

Many hotels and offices use digital phone systems. Confirm that your location uses an analog phone line before using the remote monitor to send data to the PDMS database. If you are not sure what type of phone line is available contact the hotel front desk or the office administrator and ask them.

CAUTION: DO NOT connect your remote monitor laptop to any type of digital phone line such as phone systems used in many hotels and offices, phone service provided by cable companies, and VoIP (voice over internet protocol). The remote monitor must be connected to an analog phone line. Connecting to a digital phone line will damage the laptop and not allow you to send data to the PDMS database. You will still be able to use the remote monitor to collect data from the neurostimulator.

Traveling outside the U.S.

Since the remote monitor uses a toll-free phone number only available when dialing within the U.S., it cannot be used to send data from a location outside the U.S. Talk with your doctor in advance to find out what you should do in these situations.

12. Care and Maintenance

The remote monitor and wand do not require any special maintenance and are not serviceable by patients.

- o To remove dirt or dust from the wand or laptop, wipe the outside with a soft cloth dampened with water and wrung out. **DO NOT** apply cleaning liquids or aerosols directly to the wand or laptop.

- o When not in use, the remote monitor should be turned off.

- o **DO NOT** store or transport the wand or laptop below or above their recommended storage and transport temperature ranges: 32 to 140 °F (0 to 60 °C) for the wand; -40 to 149 °F (-40 to 65 °C) for the laptop.

- o The laptop has a rechargeable battery installed. Battery power will last about 2 hours on a full charge. The battery recharges any time the laptop is plugged into an outlet but it could take about 2 hours to fully charge a drained battery. If you plan to use battery power when collecting or sending data with the laptop, make sure the battery is fully charged.

- o If you need to move the remote monitor to another location, first disassemble the pieces and store them in the carrying case.

- o **DO NOT** cover or enclose the laptop with anything that could restrict airflow through the vents and not allow heat to disperse. All laptop computers generate a moderate amount of heat when they are turned on. Restricting the airflow can damage the laptop or cause a fire.

- o A shock from the buildup of static electricity may cause the remote monitor to stop responding. One example of when a shock might occur is after you walk across a rug and then touch the laptop. If the laptop does not respond after a shock, follow the *Troubleshooting* instructions starting on page 39 to restart the laptop when it does not respond.

Return / Disposal of Laptop Computer and Wand

The laptop computer and wand should be returned to your doctor or NeuroPace if you are no longer using them. They contain electrical parts that need to be disposed of in accordance with local regulations.

13. Troubleshooting

Remote Monitor Problems

Problem:
Laptop does not turn on when the power button is pressed.

Possible Cause:
Laptop is not plugged into the electrical outlet and the battery is drained.

What to do:
Make sure the power cord is securely plugged into the outlet and into the correct spot on the remote monitor. If using the laptop battery for power, make sure it is fully charged. The laptop must be connected to an outlet for at least 2 hours for the battery to be fully charged.

Problem:
When fully charged the laptop battery power lasts less than 1 hour.

Possible Cause:
The laptop battery can no longer hold a charge and needs to be replaced.

What to do:
Contact NeuroPace Customer Support for a replacement battery.

Problem:
The laptop does not respond to keyboard/touchpad commands.

Possible Cause:
There may be a problem with the laptop operating system.

What to do:
Press and hold the power button until the laptop turns off. Restart the laptop by pressing the power button. If the problem persists, contact NeuroPace Customer Support for assistance.

<u>Problem:</u>

"Remote Monitor is locked" appears on the screen when you turn the laptop on.

Possible Causes:
- o The laptop is on and has been running on battery power for 30 minutes, but has not been in use.

- o The laptop is on but the display was closed and then opened again.

What to do:
- o Press and hold Ctrl, Alt, and Delete on the keyboard. The login screen appears. Enter NPUser as the User name if it does not appear in the "User name" box. Then press the enter key or click the arrow button.

- o If the laptop battery level is low plug the laptop into an outlet.

Login Problems

<u>Problem:</u>

"The user name or password is incorrect" appears on the screen.

Possible Cause:

An incorrect user name or a password was entered.

What to do:

Enter NPUser (no spaces between the letters) as the User name. You should not type anything in the Password box. Then press the enter key or click the arrow button. See ***Log in to the Remote Monitor*** (page 19).

<u>Problem:</u>

The login screen appears but it will not let me enter a User name. The User name and Password boxes look grayed out.

Possible Cause:

There were six failed attempts to enter the correct NPUser User name.

What to do:
Press and hold the power button until the laptop turns off. Restart the laptop by pressing the power button. Press and hold Ctrl, Alt, and Delete on the keyboard until the login screen appears. Enter NPUser as the User name. You should not type anything in the Password box. Then press the enter key or click the arrow button. See *Log in to the Remote Monitor* (page 19).

Wand Problems

<u>Problem:</u>
The wand signal strength is very low, absent or the signal is erratic.

Possible Causes:
- The wand may be loosely connected, disconnected from the laptop or plugged into the wrong port.
- The wand is not positioned properly over the neurostimulator.
- The cupped side of the wand is not facing the neurostimulator.
- There is a lot of interference from another nearby electronic device.

What to do:
- Make sure the wand is properly connected to the laptop and you have positioned the cupped side of the wand directly over the neurostimulator.
- Retest the wand signal. If the signal is low or bouncing up and down, move the wand closer to the neurostimulator to see if signal quality improves. If the signal quality is low, a nearby electronic device (e.g., another computer, television, microwave, etc.) may be causing interference. Try unplugging the laptop from the electrical outlet. Make sure the battery is charged before doing so. If this does not solve the problem, try moving the remote monitor to another location and then retest the wand signal.
- If your wand signal continues to be a problem, contact NeuroPace Customer Support for assistance.

Data collection problems

<u>**Problem:**</u>

One of the following messages appears on the screen:

"Telemetry has been lost. Reposition the Wand and try again."

"Unable to communicate with the Neurostimulator. The Wand may not be properly connected. Please reconnect the Wand and select Retry or select Cancel to continue."

Possible Causes:
- o The wand was moved while collecting data from the neurostimulator.
- o The wand cord may be loosely connected or disconnected from the laptop USB port.
- o There is interference from a nearby electronic device.

What to do:
- o Use the signal strength bar on the screen to help you position the wand over the neurostimulator to maximize signal strength. The cupped side of the wand should be facing the neurostimulator. Data collection should continue when the signal strength is high.
- o Make sure the wand is properly connected to the laptop. If this does not solve the problem, try plugging the wand cord into a different USB port.
- o If the signal quality is low, a nearby electronic device (e.g., another computer, television, microwave, etc.) may be causing interference. Try unplugging the laptop from the electrical outlet. Make sure the battery is charged before doing so. If this does not solve the problem, try moving the remote monitor to another location and then retest the wand signal.

Data sending problems

<u>**Problem:**</u>

The following message appears on the screen:

"There was an error encountered while communicating with the PDMS. Error Description: There is no dial tone. Please try again later."

Possible Causes:
- The remote monitor is connected to a digital phone line instead of an analog phone line.
- There is no dial tone because the phone line is disconnected, out of service or requires an outside line.
- The phone cord is not properly connected to the laptop or wall jack.
- Pulse rather than tone dialing was selected by mistake on the edit location screen.
- Data transmission interrupted by outgoing call on same phone line.
- Data transmission interrupted by incoming call waiting signal.
- The PDMS database is currently unavailable.

What to do:
- Make sure you have an analog phone line. You must be connected to an analog phone line or you may damage the remote monitor (see *Set up the Remote Monitor* on page 13).
- Plug a phone into the wall jack to confirm there is a dial tone. If not, contact your phone service provider.
- Check the phone cord connections (see *Set up the Remote Monitor* on page 13).
- Check that "Tone" dialing, rather than "Pulse" dialing is checked on the edit location screen. Contact NeuroPace Customer Support for assistance.
- Make sure no one else is making an outgoing phone call on the same line shared by the remote monitor.
- Make sure call waiting is disabled if you have this feature (see *Disable Call Waiting* on page 32).
- If you still have difficulty sending data, try again in an hour and then the next day. If you are still having trouble, then contact NeuroPace Customer Support.

Problem:
The following message appears on the screen:

"The connection with the server has been reset."

Possible Cause:
The phone cord may have become disconnected from the laptop or wall jack.

What to do:
Check the phone cord connections and try to send the data again (see *Set up the Remote Monitor* on page 13).

Problem:
Sending data to the PDMS database is taking a long time.

Possible Cause:
- o   There may be a problem with the PDMS database or with your phone service.
- o   A large amount of data is being sent to the PDMS database.

What to do:
- o   Wait and send data to the PDMS database on the next day.
- o   Always allow up to 20 minutes for data to be sent.
- o   Send data to the PDMS database more frequently.

14. Electromagnetic Emissions and Immunity

Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. The RNS® System is designed to be immune from common sources of electromagnetic interference. The most common sources of EMI are discussed below. The warning regarding *Electromagnetic Interference (EMI)* on page *7* lists its possible effects.

The following table lists potential EMI sources found in hospital or medical environments that are contraindicated. DO NOT have any of the following medical procedures if you have the RNS® System implanted.

Item or procedure	Contraindicated
Diathermy treatment	X
Electroconvulsive therapy	X
MRI	X
Transcranial magnetic stimulation (TMS)	X

For your convenience, the following tables list potential EMI sources alphabetically using these headings:

- o **Should not affect operation:** Commonly used items that should not affect the operation of the neurostimulator.
- o **Avoid or exercise caution:** You should avoid or exercise caution when in the presence of potential sources of EMI that may affect the operation of the neurostimulator system.

Hospital or Medical Environments

You should always inform healthcare personnel that you have an implanted RNS® System (and show your medical implant identification card) before any procedure is performed. Most diagnostic procedures, such as x-rays and ultrasounds, may be performed without affecting the RNS® System. However other diagnostic and therapeutic equipment with higher energy levels may interfere with the RNS® System. Refer to the *Warnings and Cautions* section on page *4* for specific information.

Item or procedure	Should not affect operation	Avoid or exercise caution
Computerized tomography (CT or CAT) scans		See warning, page 4
Diagnostic ultrasound	X	
Diagnostic X-ray	X	
Electrolysis		See warning, page 4
Implanted cardiac devices		See warning, page 5
Lithotripsy		See warning, page 4
Medical procedures and dental work		See caution, page 9
Other active implanted medical devices		See caution, page 10
Radiation therapy		See warning, page 4
Explantation and EMI considerations		See caution, page 10

Home, Work or Public Environments

Item or procedure	Should not affect operation	Avoid or exercise caution
Airport security and other surveillance systems		See warning, page 8
Appliances such as washing machines, dryers, electric stoves, toasters, blenders, electric can openers, and food processors	X	
Body fat measurement scales		X
Cell phones and Bluetooth devices	X	
Electric arc welding equipment		X
Electric blankets and heating pads	X	
Electric fences		X
Electric induction heaters		X
Electric steel furnaces		X
Electric substations, power generators, and large transformers		X
Electric toothbrushes, electric shavers, and hair trimmers	X	
Household magnets and magnetic bracelets		See caution, page 9
Jackhammers		X
Microwave ovens	X	
Personal computers, electric typewriters, copiers, and fax machines	X	
Portable and mobile RF communications equipment		See warning, page 7
Power lines and transmission towers		X
Radiofrequency identification (RFID) sources		See warning, page 8
Stun guns		X
Televisions, AM/FM radios, stereos, personal music players	X	
Vacuum cleaners and electric brooms	X	

For additional information about devices that generate electromagnetic interference contact NeuroPace. If you suspect EMI is disrupting the operation of your neurostimulator move away from the source of the EMI.

Guidance and Manufacturer's Declaration

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided. This declaration applies for the following devices:
- o RNS® Neurostimulator, model RNS-300M.
- o Programmer, model PGM-300.
- o Wand, model W-02.
- o Remote monitor, models DTR-300 and DTR-300-E.

The devices comply with IEC 60601-1-2, ISO 14708-3, and FCC 47 CFR Parts 2 and 15.

- o This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. The devices may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements. It may be necessary to take mitigation measures, such as re-orienting or relocating the devices or shielding their location.

Emissions and Immunity Information

The devices are intended for use in the electromagnetic environment specified below. The customer or user of the system should assure they are used in such an environment.

Table 1. Guidance and manufacturer's declaration –
electromagnetic emissions – for all equipment and systems

Emissions test	Compliance	Electromagnetic environment – guidance
Conducted emissions (CISPR 11)	Class B, Group 1 150 kHz to 30 MHz	The RNS® System uses RF energy only for its internal function. Nearby electronic equipment may be affected.
RF emissions (CISPR 11)	Class B, Group 1 30 MHz to 1 GHz	
Harmonic emissions (IEC 61000-3-2)	Class A Device[a]	The RNS® System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions (IEC 61000-3-3)	Limits per Clause 5 of the Standard[a]	

[a] The Wand (model W-02) was tested for harmonic emissions and flicker. Other products were excluded from harmonic emissions and flicker testing.

**Table 2. Guidance and manufacturer's declaration –
electromagnetic immunity – for all equipment and systems**

Immunity test	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 2, 4, 6, 8[a] kV contact discharge ± 2, 4, 8, 15[a] kV air discharge	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 (IEC 61000-4-4)	± 2 kV for power supply lines ± 1 kV for input / output lines[b]	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth[c]	
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	0% UT 0.5 cycle 0% UT 1 cycle[d] 40% UT 5 cycles[d] 70% UT 25 cycles 0% UT 5 Sec	If the user of the programmer and wand requires continued operation during power mains interruptions, it is recommended that the programmer and wand be powered from an uninterruptible power supply or a battery.
Magnetic immunity (IEC 61000-4-8)	3, 30[e] A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

[a]   Immunity to ESD tested to ±8 kV contact and ±15 kV air with Wand (model W-02).
[b]   Immunity to electrical fast transients on I/O lines tested with Wand (model W-02)
[c]   Immunity to surge line to earth tested with Programmer (model PGM-300), Remote Monitor (model DTR-300-E).
[d]   Immunity to voltage dips with compliance to 0% UT 1 cycle for Wand (model W-02) and to 40% UT 5 cycles for Programmer (model PGM-300) and Remote Monitor (model DTR-300-E).
[e]   Magnetic immunity tested with Wand (model W-02) to 30 A/m.

Table 3. Guidance and manufacturer's declaration –
electromagnetic immunity – for equipment and systems that are not life supporting

Immunity Test	Compliance Level	Electromagnetic environment – guidance
Conducted RF (IEC 61000-4-6)	3 Vrms 150 KHz to 80 MHz 6 Vrms ISM bands[a]	Portable and mobile RF communications equipment should be used no closer to any part of the RNS® System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**[b, c]
Radiated RF (IEC 61000-4-3)	3, 10, 20 V/m 80 MHz to 2.7 GHz[e]	$d = 1.17\sqrt{P}$ (80 MHz to 800MHz) $d = 2.33\sqrt{P}$ (800 MHz to 2.7 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[d], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

[a] Conducted immunity of the Wand (model W-02) compliant to 6 V/m in the ISM bands.

[b] Separation distance relevant to Programmer (model PGM-300) and Remote Monitor (model DTR-300). At 80 MHz and 800 MHz, the higher frequency range applies.

[c] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[d] 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 transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RNS® System is used exceeds the applicable RF compliance level above, the RNS® System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RNS® System.

[e] Radiated immunity of the Programmer (model PGM-300), Remote Monitor (model DTR-300-E) compliant to 3 V/m up to 2.5 GHz. Wand (model W-02) compliant to 10 V/m to 2.7 GHz and spot frequencies with pulse modulation and to 20 V/m in the communication passband. Spot frequencies tested are 385 MHz, 450 MHz, 710 MHz, 745 MHz, 780 MHz, 810 MHz, 870 MHz, 930 MHz, 1.720 GHz, 1.845 GHz, 1.970 GHz, 2.450 GHz, 5.240 GHz, 5.500 GHz, 5.785 GHz.

**Table 4. Recommended separation distances between portable
and mobile RF communications equipment and the RNS® System –
for equipment that are not life-supporting[a,b,c]**

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

[a] Separation distance relevant to Programmer (model PGM-300) and Remote Monitor (model DTR-300). At 80 MHz and 800 MHz, the higher frequency range applies.

[b] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[c] For transmitter rated at a maximum output power not listed above, the recommended separation distance of 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.

15. Specifications and Characteristics

Wand

Dimensions (Length x Width x Depth)	7" x 3.5" x 1.3" (18 cm x 9 cm x 3 cm)
Weight	0.4 pounds (181 g)
Power source	USB port of the remote monitor laptop
Operating conditions	Temperature: 32 to 95 °F (0 to 35 °C) Humidity: 15 to 90%, non-condensing Atmospheric pressure: 700 to 1060 hPa
Material	ABS copolymer
Least favorable working conditions	Wand output power and data rate vary with communication distance. Communication at a far distance (3 cm), indicated by a low signal level when using the wand, results in the slowest rate of transmission at the highest output power.
Storage and transport temperature	32 to 140 °F (0 to 60 °C)
Expected service life	5 years

Laptop Computer*

Dimensions (Height x Width x Depth)	1.3" x 13.7" x 9.4" (3.3 cm x 35 cm x 24 cm)
Weight	4.5 pounds (2 kg)
Power source	100 – 240 VAC, 1.7 A or internal rechargeable battery
USB Power supply	5V, 500 mA
Operating temperature	32 to 95 °F (0 to 35 °C)
Storage and transport temperature	-40 to 149 °F (-40 to 65 °C)

These are typical, approximate values. Your laptop may be different.

RNS® System Wireless

Wireless technology Type	Short Range, Low Power Inductive Telemetry
Frequency Band of Transmission	20 kHz – 50 kHz
Frequency Band of Reception	20 kHz – 50 kHz
Receive Bandwidth of the Neurostimulator	100 kHz
Receive Bandwidth of the Wand	≥ 50 kHz
Number of Channels	Single Channel
Modulation Type	On/Off pulse amplitude modulation
RF Data Flow characteristics	Half duplex
Effective Radiated Power	224 pW or less

16. If You Need Help

Contact your doctor as soon as possible if:

- o You are experiencing seizures with greater frequency or severity than before.
- o You are having any type of medical emergency.
- o You want to check if you can undergo a certain medical procedure or treatment while you have the RNS® System implanted.
- o You are unable to collect and send data to the PDMS database as your doctor has directed.

Contact NeuroPace Customer Support if:

- o You need help setting up or using the wand and remote monitor
- o You want to make sure your current phone lines and equipment will work with the remote monitor
- o You need to replace any part of the wand or remote monitor
- o You need more information about what to do when traveling through airport security and other surveillance systems

NeuroPace, Inc.
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Mountain View, CA 94043 USA

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Website: www.NeuroPace.com