℞ Only

NeuroPace® Patient Materials

NEUROPACE

RNS® System Patient Manual

For the RNS® Neurostimulator Model RNS-300M and Model RNS-320 and the Remote Monitor Model 5106

Read this manual before use. This manual is not meant to take the place of advice from your doctor. For a complete discussion of indications for use, contraindications, warnings, cautions, and potential side effects talk with your doctor.

DN 1022549 Rev. 1

Date: 2025-04

Contents

FCC Information

The following is communications regulation information on the neurostimulator models RNS-300M and RNS-320, and wand model W-02.

- Neurostimulator model RNS-300M FCC ID: WBWRF300
- Neurostimulator model RNS-320 FCC ID: WBWRF320
- Wand FCC ID: WBW5200 or WBW902

These components comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) These devices may not cause harmful interference, and (2) these devices 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

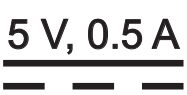
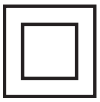
Medical Electrical Equipment needs special precautions regarding EMI and the following precautions should be taken before use.

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 on page 58*** for more information.

Symbols

SYMBOLS				
Explanation of symbols on product or package labeling				
Symbol	**Explanation**		**Symbol**	**Explanation**
	Caution			Temperature limits during use
	MRI Unsafe			Temperature limits during storage or transport
	MR Conditional			Manufacturer
	Prescription Only			Ethernet Connection (Network Connection)
	Serial Number			Type BF applied part
	Direct current (DC) 5 V (volts), 0.5 A (amperes)			Class II electrical protection
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.			

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***.

Note: Images in this manual are representative and may vary in detail from what a particular user experiences.

Safety Information

There are benefits and risks associated with all medical devices and treatments. Talk to your doctor about the benefits and risks of the RNS® System and whether it is appropriate for you. Your doctor can also answer questions regarding the information in this manual.

RISKS OF SURGERY AND TREATMENT

There are health risks associated with using the RNS® System. Risks include complications from surgically implanting the neurostimulator and leads. They also include potential risks related to the performance and use of the RNS® System. Discuss these risks with your doctor.

The risks of the surgery to implant the RNS® Neurostimulator and leads are comparable to other surgical procedures to treat epilepsy and to implant brain stimulators for Parkinson's disease. Risks associated with surgical implantation and treatment with the RNS® System include post-implant infection (7%) and bleeding in the brain or under the skull because of the implant (4.7%). There are also risks of infection and bleeding with surgery to replace or remove the neurostimulator and leads. There were other events which occurred during the studies which may or may not be related to treatment with the RNS® System. These included psychiatric symptoms (39.8%), changes in seizures (16%), and seizure related injury (49.2%), including seizure related head injury (10.5%). Eleven (11) patients died during the study. No patient died of a complication of a surgery related to the neurostimulator or leads. Patients with epilepsy, especially severe epilepsy, have a risk for sudden death (SUDEP). Seven (7) patients died from probable, possible or definite SUDEP, two patients died by suicide, one patient died of lymphoma, and one patient died of complications due to status epilepticus. Although some patients in the RNS® System studies died of SUDEP, there is no current indication that the risk of SUDEP in persons treated with the RNS® System is higher than expected for people with severe epilepsy.

Refer to Clinical Studies: Risks and Benefits on page 18 for more information.

The neurostimulator delivers electrical stimulation to the brain when it detects brain activity that your doctor feels could show the start of a seizure. You should not feel the stimulation but it is possible that you might feel a brief tingling sensation in your scalp or pain in your head. If you do, talk to your doctor so that changes can be made to the neurostimulator settings.

NEUROSTIMULATOR/LEAD REPLACEMENTS AND FAILURES

For a full discussion of what to expect for the initial implant surgery refer to Implant Surgery on page 12. The model RNS-300M neurostimulator should work for about 2.6 to 4.3 years and the model RNS-320 neurostimulator should work for about 6.0 to 12.4 years with typical use before the battery power is drained. How long your battery lasts depends on which model of neurostimulator you have and the programming settings prescribed by your doctor. When the battery power gets very low, the neurostimulator will need to be surgically replaced with a new one. Your doctor will let you know when the neurostimulator needs to be replaced. The surgery involves first making an incision in your scalp. Then the surgeon will remove the old

neurostimulator from its holder secured in the skull, and replace it with a new one. This surgery has less risk than the first surgery to implant the neurostimulator and leads because the doctor will not have to do any surgery on the bone and will not need to insert or move any of your leads. In many instances, this is done as an outpatient procedure and usually takes about one hour. As with any surgery, there are risks.

During the clinical trials, some patients had pain at the incision site and infection after replacement.

If the RNS® System is not working properly, it may not provide the right amount of stimulation at the right time. If the neurostimulator is not working properly, you will need to have it replaced. If the leads are not working properly, then the neurosurgeon may suggest that the leads be changed. Sometimes, your doctor may want to change the leads that are connected to your neurostimulator. If these leads have already been implanted, the procedure is like the neurostimulator replacement and can be done as an outpatient procedure in an hour or less (compared with 2 to 5 hours for the first surgery). If new leads are inserted, then the procedure will be more like the initial implant surgery. Refer to Clinical Studies: Risks and Benefits on page 18 for more information.

You may not be aware of problems with the performance of the neurostimulator or leads unless you are having more frequent or more severe seizures than before. So it is important that you 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 maintain a Wi-Fi connection to allow data to be sent the PDMS database automatically. If there is a concerning change in your seizures, you should also collect and send data to the PDMS database on a more frequent basis so that your doctor is able to decide whether any adjustments to the neurostimulator settings should be made. Read this manual for more information.

People using the RNS® System will not be able to undergo certain medical procedures. These are procedures that might damage the neurostimulator/leads, or cause injury and even death. A list of these procedures can be found in ***Contraindications on page 15***, ***Warnings on page 6***, and ***Cautions on page 9***.

Warnings

WARNING: 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.

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

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 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.

WARNING: MRI Safety Information

RNS® Neurostimulator model RNS-320: You must consult your doctor to determine whether an MRI scan is possible for you. The RNS® System (with RNS Neurostimulator model RNS-320) is MR Conditional, which means that an MRI scan may be safely performed under specific conditions. It may also be possible to have an MRI scan if your neurostimulator has been explanted. If your doctor determines it is possible for you to have an MRI scan, he or she must make sure that the conditions for a safe MRI scan are followed. Those conditions include putting your neurostimulator in MRI Mode, which uses more battery and may affect battery life. While in MRI Mode, the neurostimulator is not detecting or delivering therapy to the patient. Therefore, you should work with your doctor to minimize the time your neurostimulator is in MRI Mode.

RNS® Neurostimulator model RNS-300M: DO NOT have a Magnetic Resonance Imaging (MRI) scan if you have an RNS® System with an RNS Neurostimulator model RNS-300M implanted. The RNS Neurostimulator model RNS-300M is MR Unsafe. Having an MRI scan with an RNS Neurostimulator model RNS-300M implanted may result in serious injury or possible death.

RNS® System External Components: All external components such as the magnet, wand and remote monitor are MR Unsafe and can pose a projectile hazard, and therefore, must be kept out of the MRI scanner room.

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

WARNING: Interaction with Implanted Cardiac Devices

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

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

WARNING: Adverse Tissue Reaction

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

WARNING: Chronic Tissue Stimulation

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

WARNING: Erosion

Skin erosion (breakdown of skin tissue) 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.

WARNING: Lead Migration

The implanted lead(s) may migrate (move) 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.

WARNING: Pregnant Women

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

WARNING: 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.

WARNING: 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.

WARNING: Electrical Shock

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

- DO NOT use the wand or tablet when you are wet.
- DO NOT apply water or liquids directly to the wand or tablet.
- 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 tablet during an electrical storm.
- DO NOT clean the wand or tablet with any cleaning liquids or aerosols. Wipe the outside of the wand and tablet with a clean cloth, dampened with water and wrung out. Make sure to disconnect the tablet from the electrical outlet before cleaning.

- DO NOT use the wand or tablet if you think they appear to be damaged or are not working properly.
- DO NOT attempt to modify or repair the wand or tablet. 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 tablet.

WARNING: 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.

WARNING: 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 on page 58*** for more information.

WARNING: 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 on page 58*** for more information.

WARNING: 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.

WARNING: 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.

WARNING: 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, security tag deactivators, 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).

WARNING: 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.

WARNING: Cables

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

Cautions

Caution: 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.

Caution: 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.

Caution: Magnet

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

Caution: Household Magnets and Magnetic Bracelets

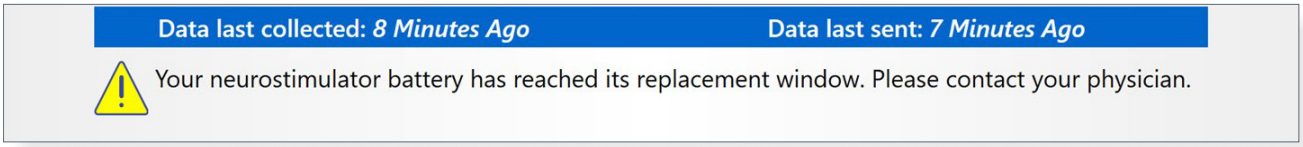
DO NOT put items that contain magnets within 4 inches of the neurostimulator. Magnets contained in such products as stereo speakers, AM/FM radios, power tools, cellular, cordless and conventional phones, as well as magnets used therapeutically or worn on the body may interfere with stimulation. Since 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.

Caution: 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 Replacement Indicator

When your neurostimulator battery is low, the remote monitor will show the following message on the Home screen: "Your neurostimulator battery has reached its replacement window. Please contact your physician."



NeuroPace recommends you act on this message and contact your physician about replacing your neurostimulator.

Caution: Neurostimulator Longevity

High and frequent levels of stimulation reduce neurostimulator battery longevity.

Caution: Removal 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, lead 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 on page 58*** for more information.

Caution: Lead Replacement and Leads Left in Place

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

Caution: 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.

Caution: 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.

Caution: Patient Population for Which Safety and Efficacy Have Not Been Established

The safety and effectiveness of the RNS® System has not been established for:

- People with generalized epilepsy
- People with a seizure focus that cannot be adequately localized
- Pregnant women
- Nursing mothers
- People under the age of 18
- People with simple partial sensory seizures only
- People with less than three seizures a month on average
- People who have more than two epileptic foci
- People who have not failed two antiepileptic drugs

Caution: Safety and Effectiveness Beyond 24 Months

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

Caution: Remote Monitor Tablet

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

Caution: Data Collection

You should collect data from the neurostimulator as directed by your doctor. If connected to a Wi-Fi network, the remote monitor sends data automatically to the PDMS database. NeuroPace recommends you collect data from the neurostimulator at least once a day and maintain a Wi-Fi connection to allow data to be sent the PDMS database automatically. By receiving 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 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 data 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 as directed.

Caution: Operating Temperatures

DO NOT use the wand or tablet in temperatures above or below the recommended operating range (32°F - 95°F). The wand or tablet 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.

Caution: 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.

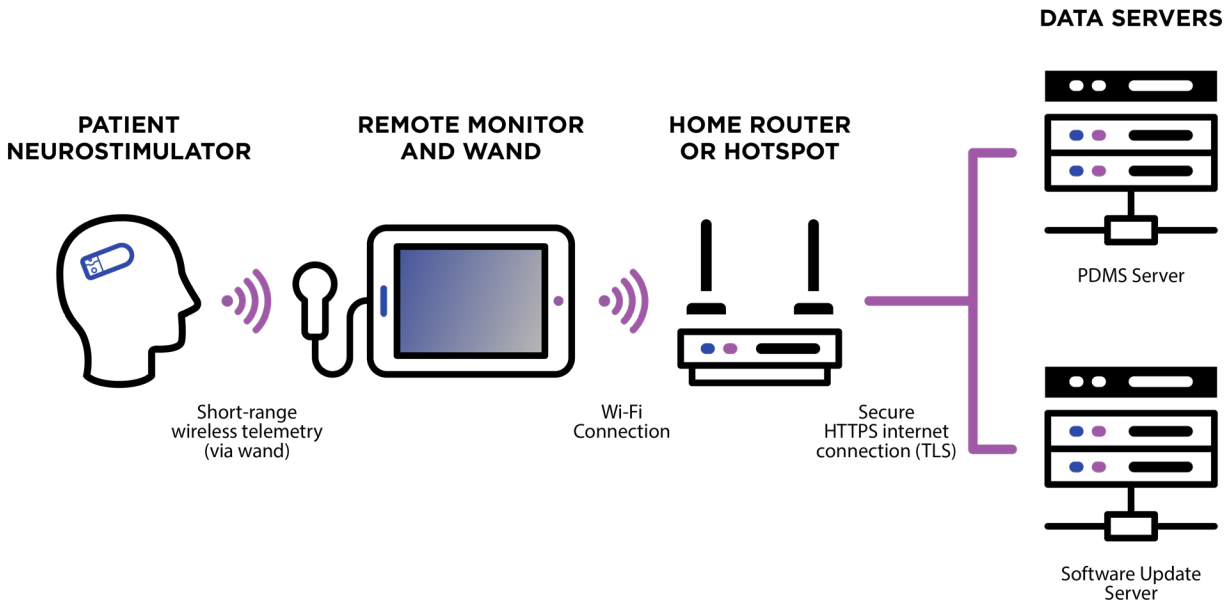
DO NOT move the remote monitor to another location without first disconnecting the parts and storing them in the carrying case. Disconnect the wand and all cords from the tablet. You may damage the parts if you do not disconnect them before moving them.

Caution: Heating

The remote monitor's AC adapter may become hot during normal operation. Use care when handling during or immediately after operation.

Cybersecurity, Device Security, and Patient Information

The following diagram illustrates the NeuroPace® Remote Monitor network architecture in the home environment.



The NeuroPace® Remote Monitor uses a short-range wireless link between the wand and the neurostimulator to collect the data stored on the neurostimulator. The remote monitor securely uploads this information to the PDMS using a Wi-Fi connection. Wi-Fi is also used to download software updates to the remote monitor. These processes are designed to reduce cybersecurity risks and protect data from being read by anyone except those authorized by the patient.

- Data communicated between the remote monitor and the PDMS via the Internet are encrypted using HTTPS (TLS). The remote monitor will upload patient data only to the PDMS.
- The remote monitor only runs the NeuroPace application. The remote monitor does not have a web browser for other Internet communications.
- The remote monitor uses Windows firewall software, which provides strong anti-virus and anti-malware protection, prevents unwanted connections and logs security events and issues.
- The remote monitor deletes a patient's Protected Health Information (PHI) after upload of the information to the PDMS is complete.
- The remote monitor hard drive is encrypted with AES-256 security so data cannot be accessed if the device is lost or stolen.
- NeuroPace maintains regular security patches for the Windows operating system.

WIRELESS INFRASTRUCTURE REQUIREMENTS

The NeuroPace® Remote Monitor requires a Wi-Fi connection to upload data to the PDMS. This may be through a home wireless router or another available Wi-Fi network that does not require a web browser to create an account for the connection. The network must allow Internet communications on Port 443 for the encryption software used between the remote monitor and the PDMS.

BACKUP AND RESTORE FUNCTION

Data downloaded from your neurostimulator is deleted from the remote monitor after it is uploaded to the PDMS. The remote monitor does not store therapy settings or other patient-specific information. Therefore, the remote monitor does not need to be backed up or restored and any remote monitor will work with your neurostimulator.

SECURE USB CONNECTION

The USB port on the remote monitor is designed to work only with the Wand. Do not connect anything other than the Wand to the USB port.

SOFTWARE SECURITY UPDATES

NeuroPace issues software updates periodically to help secure the RNS System, including the remote monitor. Software security updates should be installed as soon as possible. See the ***NeuroPace Update Center on page 45*** for more detail.

SECURITY EVENTS

The Windows security software logs security events and issues but security notifications are not displayed during normal operation.

If your remote monitor becomes unresponsive or does not function as expected or if your remote monitor is lost or stolen, please contact NeuroPace Customer Support.

About

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.

CONTRAINDICATIONS

The RNS® System should not be used by people who:

- Are at high risk for surgical complications such as active systemic infection, coagulation disorders (such as the use of anti-thrombotic therapies) or platelet count below 50,000.
- Have another medical device implanted that delivers electrical energy to the brain.
- Are unable, or do not have the necessary assistance, to properly operate the NeuroPace® Remote Monitor or magnet.

DO NOT have any of the following medical procedures if you have the RNS® System implanted. These procedures produce energy that can travel through the neurostimulator and leads to the brain, and can result in brain injury or death. Turning the neurostimulator off prior to the procedure will not prevent problems from occurring. Even if the neurostimulator has been removed, problems can arise if any part of a lead is still implanted. If you have any of the procedures listed below while you have the RNS® System implanted, it may result in serious injury or possible death.

- Diathermy – High-frequency electromagnetic radiation, electric current or ultrasonic waves to induce heat in tissue anywhere on the body, either for therapy or relaxation. You absolutely CANNOT be treated with any type of shortwave, microwave, or therapeutic ultrasound diathermy device whether or not it is used to produce heat. These treatments should not be applied anywhere on the body.
- Electroconvulsive Therapy (ECT) – Electrically-induced seizures to treat psychiatric disorders.
- Transcranial Magnetic Stimulation (TMS) – Electromagnetic current to treat psychiatric disorders.

EPILEPSY AND ITS TREATMENT

Epilepsy is a brain disorder that causes seizures. Seizures occur when there is a sudden electrical misfiring of nerve cells in the brain. These misfires can cause convulsions or spasms, confusion, staring blankly, and sometimes loss of consciousness. There is no one cause of epilepsy. Genetics, head trauma, medical and developmental disorders may all play a role. Epilepsy affects nearly 3 million Americans and 50 million people worldwide.

Epilepsy is usually treated first with antiepileptic drugs. These drugs help to prevent seizures. If a person's epilepsy cannot be brought under control after trying two or more different antiepileptic drugs, that person's epilepsy is said to be medically refractory, i.e. the likelihood of achieving seizure freedom with another antiepileptic drug is less than 5%. If a person's epilepsy is said to be medically refractory the person may be a candidate for other treatments.

TREATMENT WITH THE RNS® SYSTEM

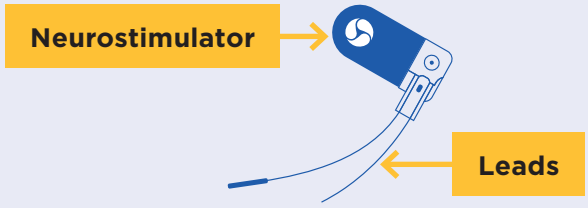
The RNS® System is designed as a treatment for medical refractory partial epilepsy with partial onset seizures, in which seizures begin in a focus in the brain and then may spread to involve other parts or even the entire brain. The RNS® System does not treat other types of epilepsy (generalized epilepsies) in which seizures arise from all areas of the brain at the same time. People who use the RNS® System will continue to take antiepileptic drugs. Your doctor will know if you have the type of epilepsy and the kinds of seizures that can be treated with the RNS® System.

ALTERNATIVE TREATMENTS FOR MEDICALLY REFRACTORY EPILEPSY

Epilepsy surgery involves removing or disconnecting the part of the brain that is triggering the seizures. Epilepsy surgery can be very helpful, but not all people with epilepsy are candidates for an epilepsy surgery that results in seizure freedom. Another treatment option for partial onset seizures is vagus nerve stimulation, which provides periodic electrical stimulation to the vagus nerve in the neck. In most cases, people who are treated with epilepsy surgery or vagus nerve stimulation continue to take antiepileptic drugs.

The type of treatment prescribed will depend on several factors. These include the frequency and severity of seizures, ability to localize seizure foci, the number of seizure foci, the person's age and overall health, and their medical history. An accurate diagnosis of the type of epilepsy is also critical to choosing the best treatment. The goal of all epilepsy treatment is to achieve seizure freedom or, if that is not possible, to control seizures, avoid the side effects of treatment, and make it possible for people to continue to lead lives that are not affected by seizures.

The RNS® System



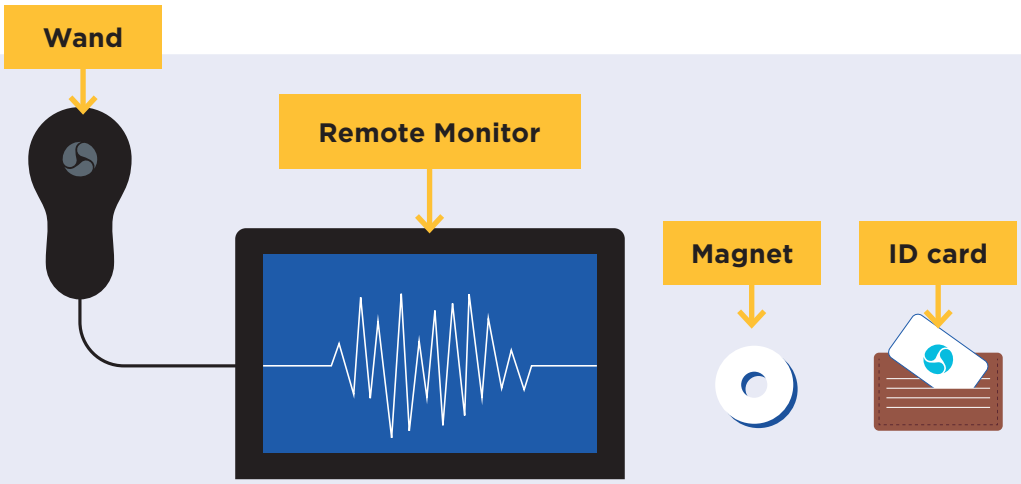
DESCRIPTION OF THE RNS® SYSTEM

A small, battery-powered device (called a neurostimulator) is surgically implanted in the skull. Wires (called leads) that are connected to the neurostimulator are placed on and/or inside the brain. The neurostimulator monitors the electrical activity of the brain and detects abnormal activity that could lead to a seizure. If abnormal activity is detected, the neurostimulator delivers electrical stimulation to the brain through the leads to help prevent the seizure before it occurs.

The neurostimulator will be programmed for initial use by your doctor after it is surgically implanted. Then the neurostimulator settings will be adjusted on an ongoing basis as needed. The programmer lets your doctor do the initial programming and follow-up adjustments to the neurostimulator. Adjustments are based on brain activity and response to stimulation, which are both stored in the neurostimulator.

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 or tablet computer, a wand and accessories.

After connecting the hand-held wand to the remote monitor, data in the neurostimulator are collected by placing the wand over the implant site. The wand uses Radio Frequency (RF) communication to collect the data. Data are stored in the remote monitor and then sent to a secure database over the internet. 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.

As part of the RNS® System, your doctor will provide you with a magnet. The magnet instructs the neurostimulator to record brain activity when you swipe it over the neurostimulator during a seizure. That way your doctor is able to identify the event during data review and make adjustments to the neurostimulator settings as needed. Another use of the magnet is to temporarily stop stimulation. (Your doctor may turn off this feature.) Although not expected to happen, you may want to stop stimulation if you think you are feeling the stimulation.

A medical implant identification card is provided that lets others know you are using the neurostimulator. Carry the card at all times. The card contains important information in the event you are being treated by another doctor who is unfamiliar with the RNS® System. You should also show this card before going through security systems at airports and other places. Refer to the Warnings on page 6 and Cautions on page 9 for specific information.

The neurostimulator remains implanted until your doctor determines that battery power is low. Then it is time to replace the neurostimulator. How long your battery lasts depends on the model of neurostimulator you have—which your doctor can tell you and is also on your Medical Implant Identification Card.

For the model RNS-300M, this is usually after 2.6 to 4.3 years with typical use; for medium stimulation and detection settings the battery is estimated to last 3.9 years. For the model RNS-320, this is usually after 6.0 to 12.4 years with typical use; for medium stimulation and detection settings the battery is estimated to last 10.8 years. At that time, the neurostimulator is removed and a new one is implanted. Unless the leads need to be replaced, the new neurostimulator will be connected to the same leads.

What to Expect with the RNS® System

Patient Manual

What to Expect with the RNS® System

Implant Surgery

BEFORE YOUR SURGERY

Your doctor will carefully examine you to locate the areas in your brain where your seizures start. This helps determine where the leads should be placed in the brain. Your doctor will also decide how many leads to implant, depending on the location of your seizures. The cortical strip lead is placed on the surface of the brain. The depth lead is placed inside the brain. Make sure your doctor explains all the risks associated with implant surgery, especially as they might relate to any other medical conditions you may have.

YOUR IMPLANT SURGERY

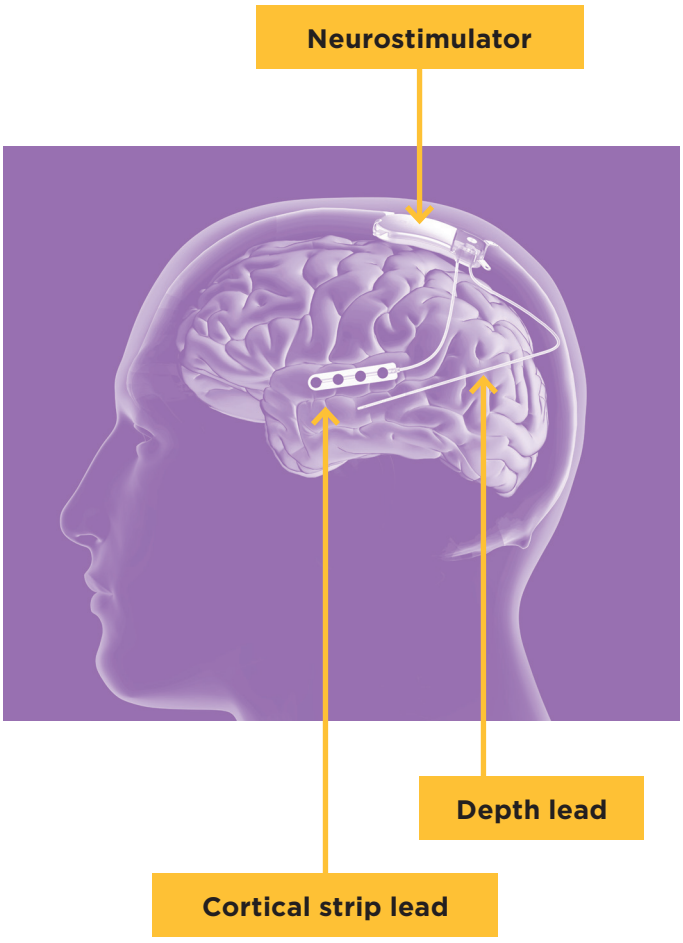
Your surgeon will determine what type of anesthesia you will need. You may be placed under general anesthesia for the neurostimulator implant.

The implantable RNS® System is made of two parts: the neurostimulator and leads (tiny wires with electrodes). The entire surgery should take approximately 2 to 5 hours.

During the procedure and while you are asleep, at least one cut, and maybe more, will be made in your scalp and skull (the exact places may vary). The cuts made for putting in the leads are about the size of a quarter, but may be larger. The cut in the skull for the neurostimulator will most often be made on the side toward the back of the head. The exact shape of the cut will be made to fit the neurostimulator. The position may be different depending on where the leads are placed and other factors. The neurostimulator is fixed in place and connected to two of the leads.

Usually two leads are implanted during the procedure. However, depending on the area where your seizures start, the doctors may decide that implanting up to four leads during the procedure may be the best option for you. No more than four leads will be implanted.

If you have more than two leads put in, only two leads will be connected to the neurostimulator. The ones that are not connected to the neurostimulator are not active and cannot deliver responsive stimulation. At a later time, the doctor may decide to change the leads connected to the neurostimulator, if needed. The inactive lead(s) could be attached to the neurostimulator and be made active during a second surgery. The surgery to connect a lead that is not active is not as major as the first surgery. Talk to your surgeon about the specific details of your surgery.



POST-SURGERY RECOVERY

You may remain in the hospital for a few days following surgery until your doctor feels it is okay for you to return home. Your doctor will also use that time to make sure there have been no complications from surgery and may program your neurostimulator for initial use. Your incision areas will be checked to make sure they are healing properly.

ONGOING TREATMENT AND MONITORING

The neurostimulator delivers electrical stimulation to the brain when it detects abnormal brain activity as determined by your doctor. You should not feel the stimulation. A few patients report that they feel the stimulation when first using the RNS® System. This side effect is usually resolved by your doctor making changes to the neurostimulator settings.

The RNS® System is designed to reduce the frequency of seizures. The majority of patients continue to experience seizures while using the RNS® System. You should expect to continue to take antiepileptic medications. Not everyone who uses the RNS® System will respond to stimulation the same way.

You will be expected to see your doctor for follow-up visits for as long as you use the RNS® System. The visits may be frequent at first and then not as often. At those visits, your doctor will adjust the neurostimulator settings based on data you have collected from the neurostimulator and sent to the PDMS database. You should talk to your doctor if you feel you are having seizures with greater frequency. It is a good idea to collect and send data to the PDMS database more frequently until your doctor is able to make adjustments.

Although the neurostimulator and leads are secured below your scalp, a blow to the head or neck may dislodge or damage them. If the parts move or are damaged, this may result in stimulation not being delivered until the neurostimulator or leads are surgically repaired or replaced. Talk to your doctor if you have had any type of head or neck trauma after you begin using the RNS® System. Although it is not known if there is a larger risk of bleeding in the brain after head trauma in patients who are implanted with the RNS® System, you should tell your doctor if you have any head trauma or injury to the head or neck.

THE NEUROPACE® REMOTE MONITOR AND WAND

The patient in the home is an intended operator of the remote monitor with wand. You will use the NeuroPace® Remote Monitor and wand to collect data from the neurostimulator and 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, if you have a laptop remote monitor, send data to the PDMS database at least once a week. If you have a tablet remote monitor and it is connected to Wi-Fi as recommended, it sends data automatically after you collect it.

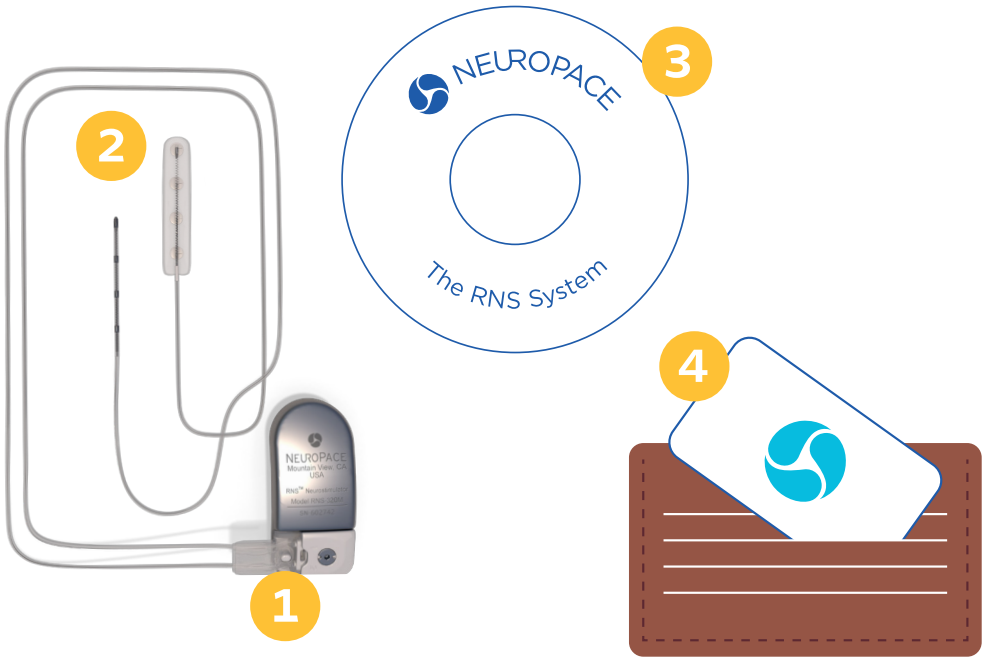
WHEN IT'S TIME TO REPLACE THE NEUROSTIMULATOR

Your neurostimulator is powered by a battery and will need to be replaced when battery power is low. The model RNS-300M neurostimulator should last 2.6 to 4.3 years with typical use and the model RNS-320 neurostimulator should last 6.0 to 12.4 years with typical use. How long your battery lasts depends on which model of neurostimulator you have and the programming settings used by your doctor.

Your doctor will be able to determine when battery power is getting low. When the battery power gets very low, the neurostimulator can be surgically removed and replaced with a new one. Replacement surgery will be less complex and should take less time than when the neurostimulator was first implanted. Unless the leads need to be replaced, the new neurostimulator will be connected to the same leads during the surgery. Your doctor may adjust the location of the leads at that time.

Parts

RNS® System Parts



1 **RNS® NEUROSTIMULATOR**

The device implanted in the skull that delivers electrical stimulation.

2 **NEUROPACE® CORTICAL STRIP LEAD AND NEUROPACE® DEPTH LEAD**

The leads are wires that connect the neurostimulator to areas of the brain where seizures start. The neurostimulator senses your brain activity and delivers electrical stimulation through these wires.

3 **MAGNET**

A device that lets you record brain activity during a seizure. The magnet also lets you temporarily stop stimulation (unless your doctor has turned off this feature).

4 **MEDICAL IMPLANT IDENTIFICATION CARD**

A wallet sized card that lets others know that you are using the RNS® System and makes them aware of procedures that may be harmful (such as an MRI), your physician's name and phone number, and which NeuroPace products have been implanted.

Using The Magnet

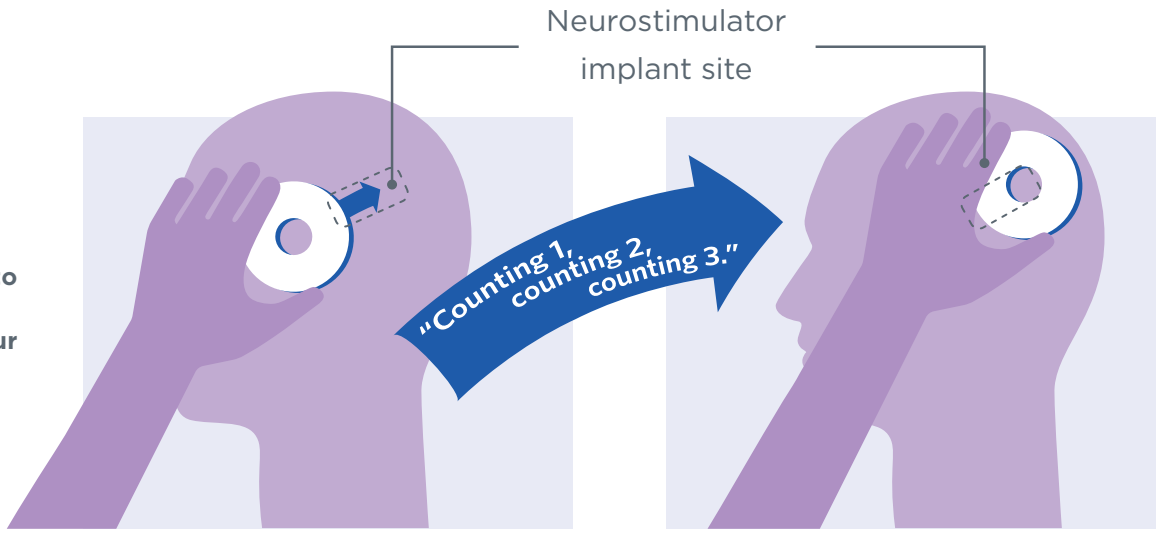
THE MAGNET HAS TWO USES

Use 1: It instructs the neurostimulator to make a recording of your brain activity when you choose. To record an event, swipe the magnet over the neurostimulator while counting to 3. For example, swipe the magnet while you say “counting 1, counting 2, counting 3.”

Talk to your doctor to find out when you should use the magnet to record your brain activity (such as when a seizure is starting). The recording will be included with the other data you collect with the remote monitor and send to the PDMS database. At your next office visit, your doctor can review your brain activity and make adjustments to the neurostimulator settings as needed.

USE 1

Swipe magnet while counting to three to make a recording of your brain activity



Use 2: It lets you temporarily stop stimulation (unless your doctor has turned off this feature). You may want to do this if you feel the stimulation. To stop stimulation, hold the magnet in place over the neurostimulator. Stimulation will be stopped for as long as you hold the magnet in place. When you move the magnet away, normal operation will resume.

The only other way to stop stimulation is by your doctor adjusting the neurostimulator settings.

USE 2

Hold magnet in place over neurostimulator to temporarily stop stimulation

Parts of the NeuroPace® Remote Monitor

Make sure you have all the parts described below.

Contact NeuroPace Customer Support at 866-726-3876 if any parts are missing.

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

1 CARRYING CASE

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

2 THE REMOTE MONITOR SOFTWARE ON TABLET COMPUTER

The remote monitor software program is already installed on the tablet computer. It stores data collected by the wand, and then sends it to the secure NeuroPace database (PDMS).The tablet computer you receive may not be the same model shown here. The location of the buttons and connections may also differ from the model shown here.

3 WAND

The Wand plugs into the tablet 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 tablet computer. The wand collects data through Radio Frequency (RF) communication.

4 POWER CORD

The power cord powers the tablet computer and charges its battery. The tablet comes with the 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 tablet computer model you receive.

Setup

Setup the Remote Monitor

FIND A GOOD PLACE TO SETUP

The remote monitor is intended to be used by the patient at home. 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.

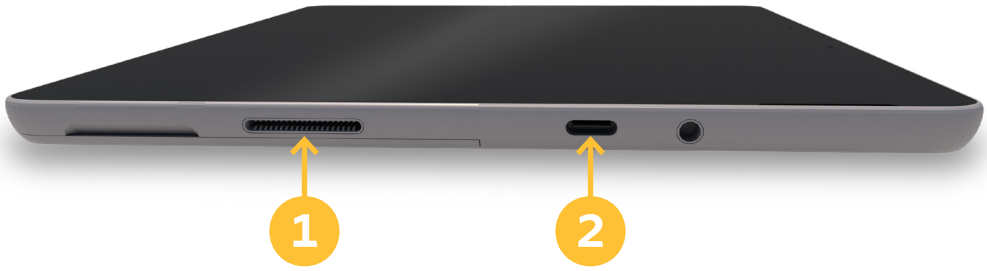
Review the ***Safety Information on page 4*** before continuing.

Find a suitable place to set up the remote monitor. This should be an area:

- Away from water, moisture or dampness that can damage the wand and tablet.
- Away from extreme temperatures (below 32°F or above 95°F) that can interfere with wand and tablet operation.
- Away from small children and pets who can damage the wand and tablet.
- Away from large electrical appliances that might be a source of electromagnetic interference (EMI) and interfere with wand and tablet operation.
- Near an electrical outlet that will accept the type of power cord plug that came with your tablet.
- In range of your Wi-Fi network.

You will not be able to confirm that there are no large sources of EMI nearby until you observe the wand signal while collecting data.
Refer to ***Get Data from Your Neurostimulator on page 37***.

CHARGE THE REMOTE MONITOR



1 **Locate the power connection** on your tablet. Plug one end of the power cord into the tablet 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 tablet to the outlet.

2 **Locate the USB port** on your tablet. Plug the wand cord into the USB port. The image below shows the remote monitor tablet with all connections made while charging.

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

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

The remote monitor is ready for use when the wand is connected, the battery is charged and the power cord is removed. See image below.

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

Turn on the Remote Monitor

Note: Before turning on the remote monitor, be sure you have completed the section ***Setup the Remote Monitor on page 27***. If this is the first time you are using the remote monitor, the tablet battery will not be fully charged until it is plugged into the outlet for about two hours.

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

1 Press the power switch near the upper corner.

When you power on the tablet, the remote monitor first checks for any software updates to install. If the remote monitor has a software update ready to install, the NeuroPace Update Center appears before you get to the Home screen. NeuroPace recommends you install all software updates right away, and it usually takes only a matter of minutes to install. For instructions, refer to ***NeuroPace Update Center on page 45***.

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

Basics

Remote Monitor Basics

The main components of the remote monitor are the tablet 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 tablet computer. If connected to Wi-Fi, the tablet then sends the data automatically to the secure PDMS database that your doctor can access. A software program installed on the tablet controls the use of the remote monitor.

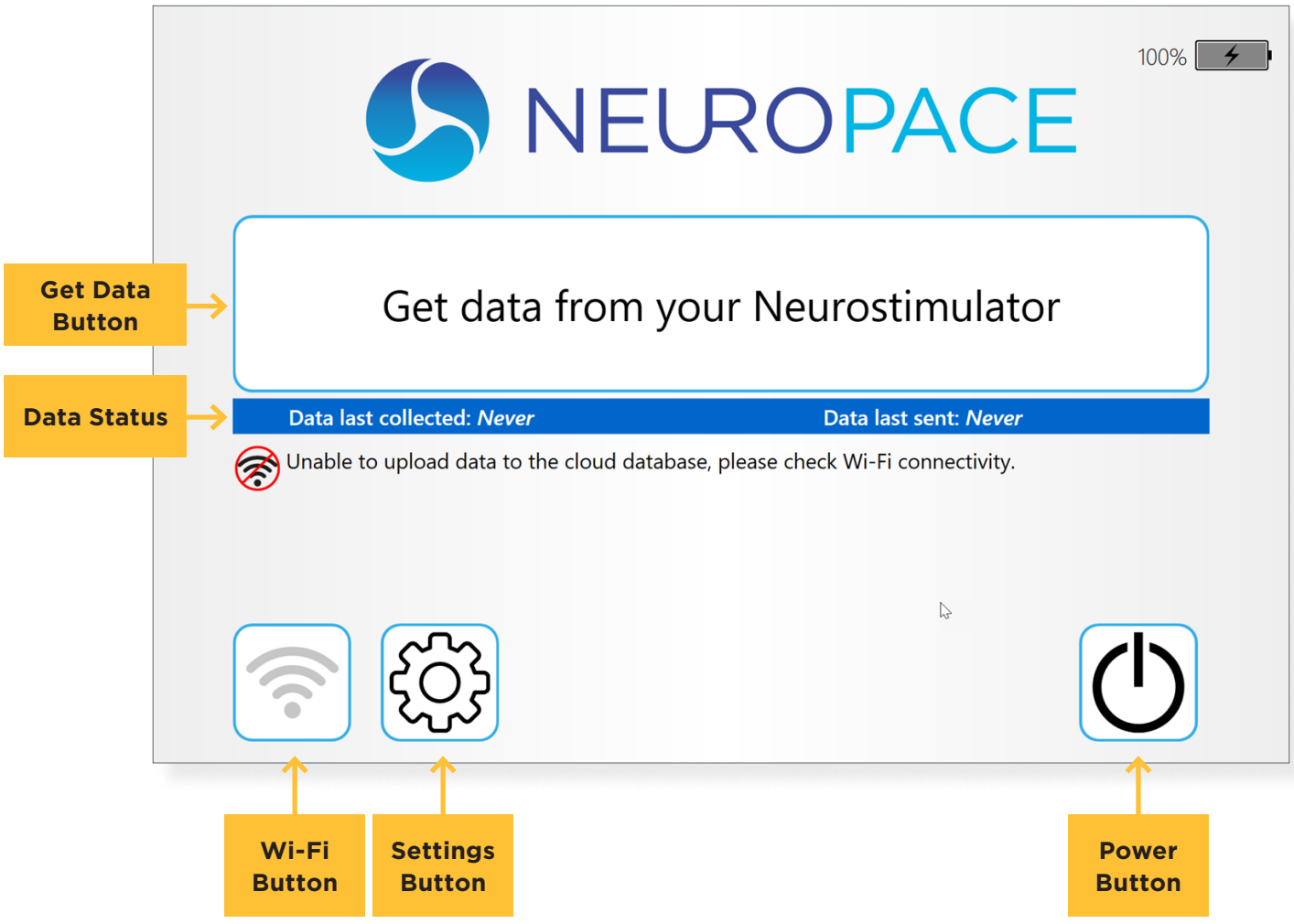
Note: Software screens that appear on the tablet and that are described below may not exactly match the screens that will appear on your tablet. This is due to differences in the type of tablet you may receive as part of the RNS® System.

TABLET TOUCHSCREEN AND BUTTONS

The remote monitor tablet is a touchscreen device; it is operated by touching elements on screen, such as software buttons. A touchscreen keyboard appears when needed to enter information, such as a password.

HOME SCREEN

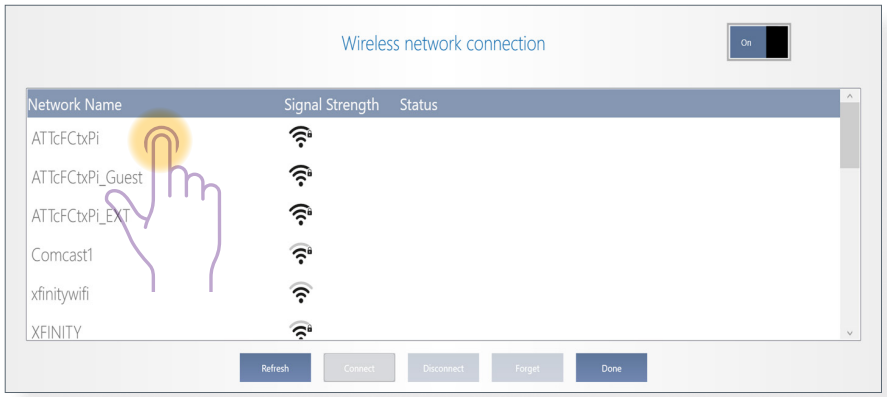
The Home screen looks like this before you connect to Wi-Fi the first time:



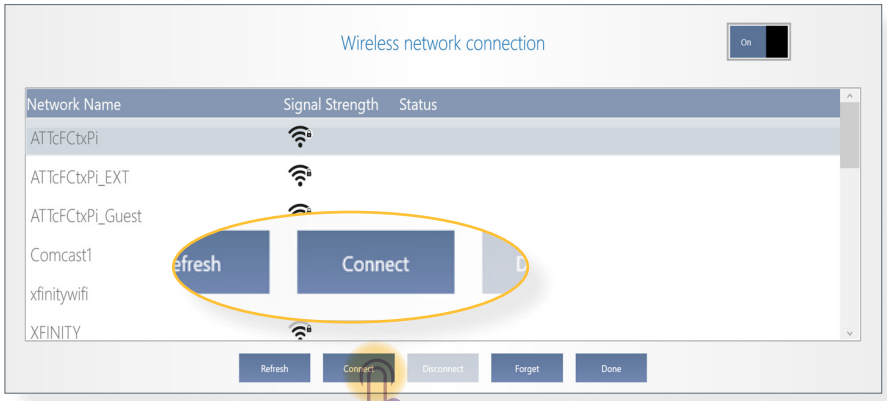
CONNECT TO WI-FI

To communicate with the NeuroPace database (PDMS), connect the remote monitor to a Wi-Fi network following the instructions below.

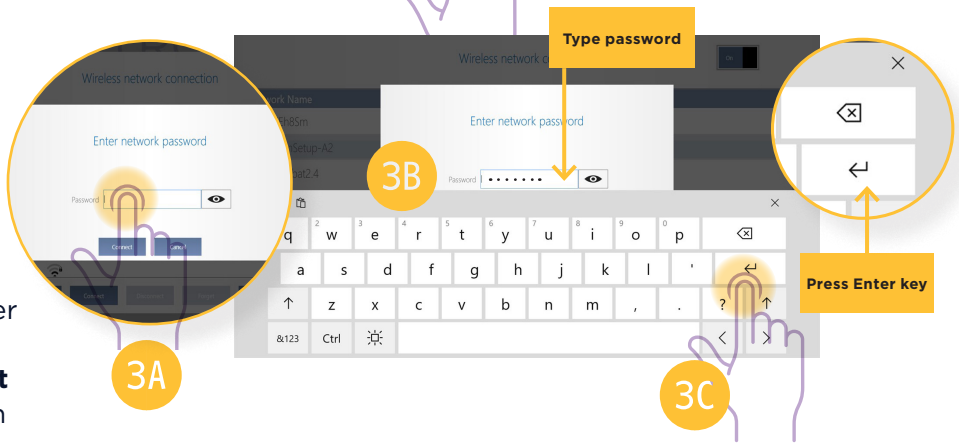
1. Touch the **Wi-Fi** button at lower left to view and select available wireless networks.



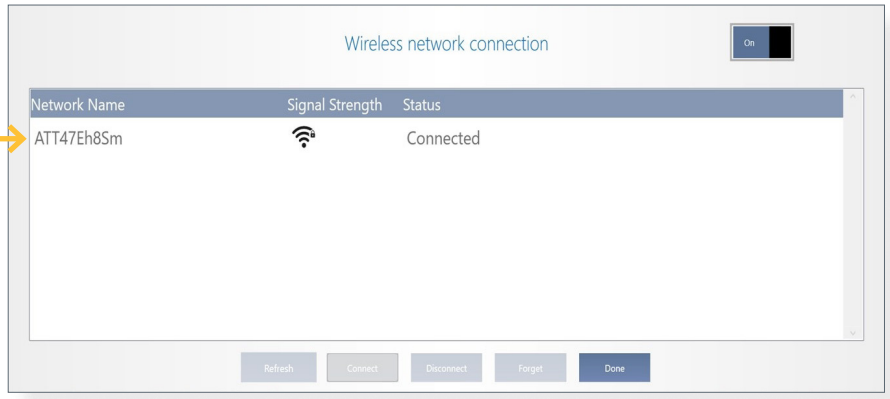
2. Touch to select the desired network and then touch the **Connect** button. If the network requires a password, a dialog pops up for you to enter the password. Otherwise, it connects right away.



3. You must touch within the **Password** field to make the on-screen keyboard appear. Use the keyboard to enter the Wi-Fi password and then press the Enter key. (Or first close the keyboard by touching the X at upper right of the keyboard and touch the **Connect** button.) You can touch the "eye" button to see the password you typed in.

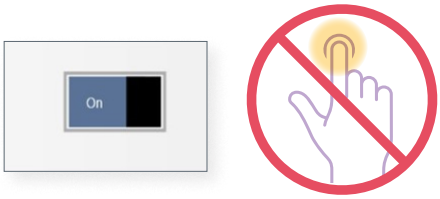


When it connects, the screen shows only the network you are connected to.



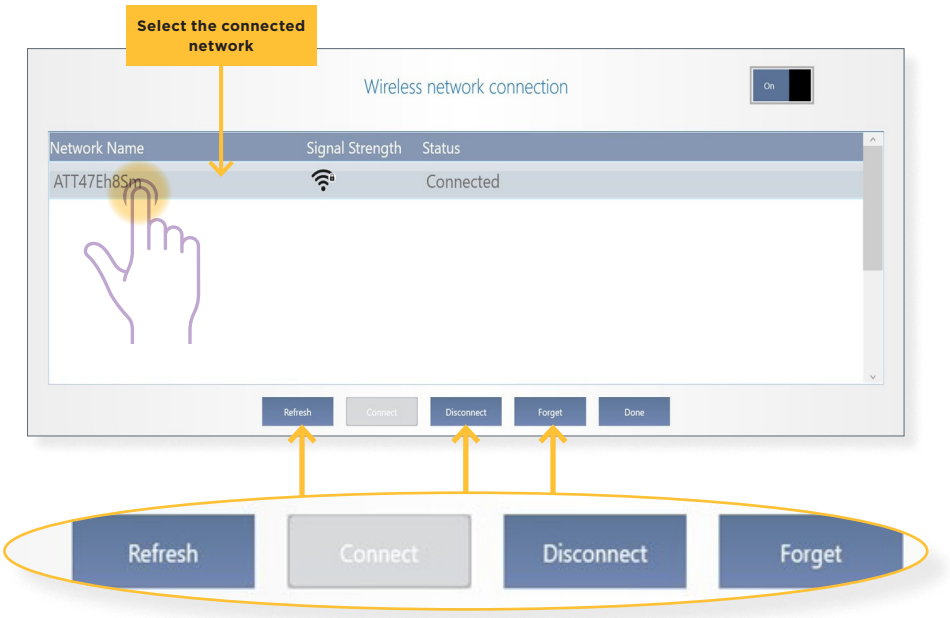
Note the following additional information and options about wireless network connections:

- The operating system remembers the passwords you enter and connects automatically to networks that you connected to before, if Wi-Fi is on. (There is an **On-Off** button at upper right. Wi-Fi is on by default and should always be left on.)

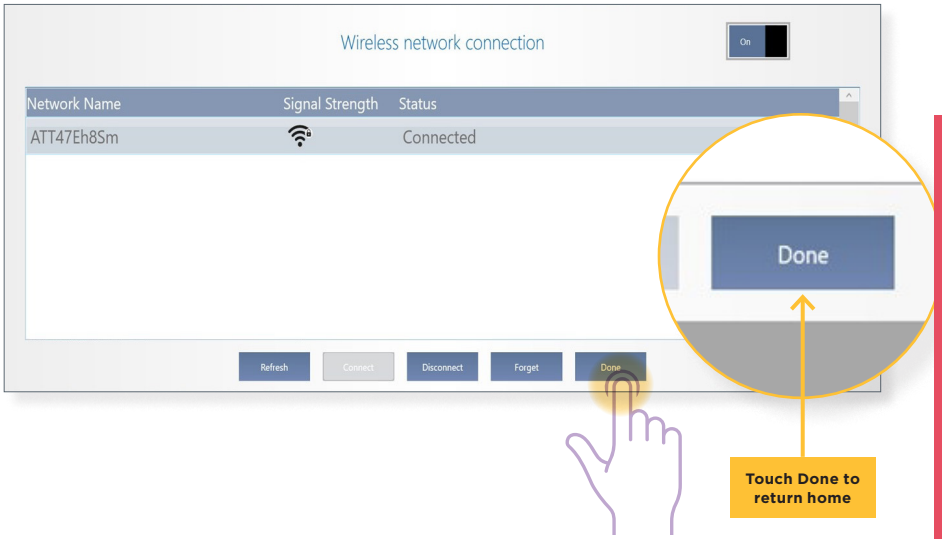


- Some public Wi-Fi networks require you to enter information into a web browser to connect to the Internet (for example, hotels or businesses). The remote monitor does not support a web browser for Internet communications, so you will not be able to enter that information to connect the remote monitor to the Internet. In this case, the remote monitor indicates you are connected to the Wi-Fi network, but you are not connected to the Internet. You must select another Wi-Fi network to upload your data to the PDMS.

- If you want to view and connect to another wireless network, you must first touch to select the connected network and then touch **Disconnect**.
- If you don't intend to connect to a network anymore, select the name and then touch the **Forget** button. If you later decide to connect to that network again, you will have to re-enter the password.
- Touch the **Refresh** button to display the list of available wireless networks. The button is active when the remote monitor is not connected to a wireless network.



4 Touch **Done** to return home.



WI-FI BUTTON ON THE HOME SCREEN

All gray bars mean the tablet is not connected to Wi-Fi, but Wi-Fi is on. This is how it looks when you first set up the tablet, until you connect to a Wi-Fi network. Touch to view available Wi-Fi networks and connect.

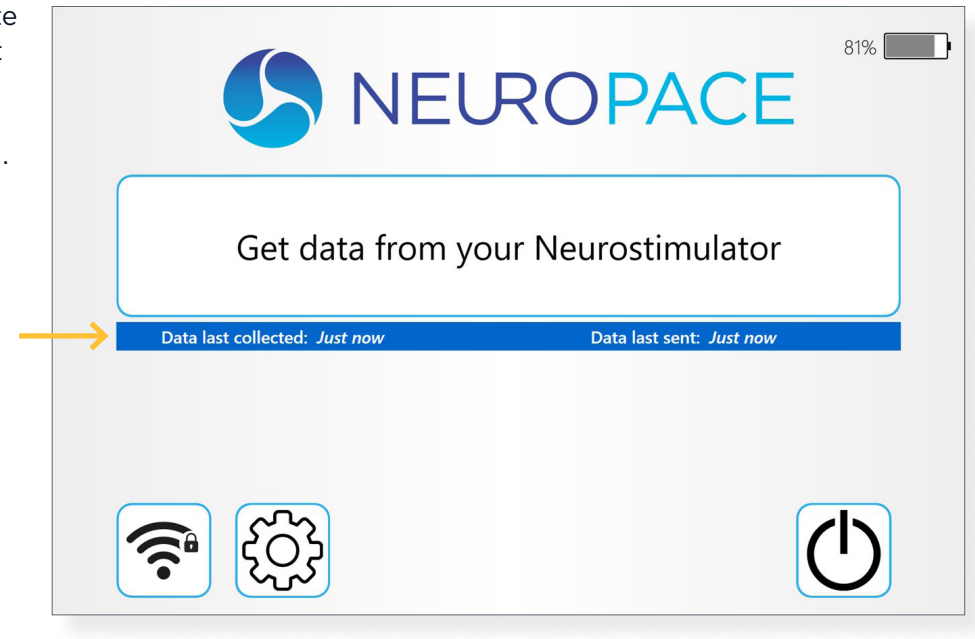
Black bars mean Wi-Fi is connected to a wireless network. The lock symbol (as shown) means the network requires a password. The tablet remembers passwords and connects automatically to networks you have connected to before. More black bars indicate greater Wi-Fi signal strength.

"OFF" with gray bars means Wi-Fi is off. Wi-Fi is on by default and should not be turned off. If it is off, touch to access the Wi-Fi On/Off button and turn on Wi-Fi.

CONFIRM REMOTE MONITOR SETUP

To confirm that the remote monitor is set up correctly, you should follow the instructions to ***Get Data from Your Neurostimulator on page 37***.

When you get data, the remote monitor automatically sends it to the PDMS database if you are connected to Wi-Fi, and reports this success on screen. If you are able to gather and send data successfully, you have properly set up the remote monitor. If not, see ***Troubleshooting on page 52*** for information on how to solve the problem.

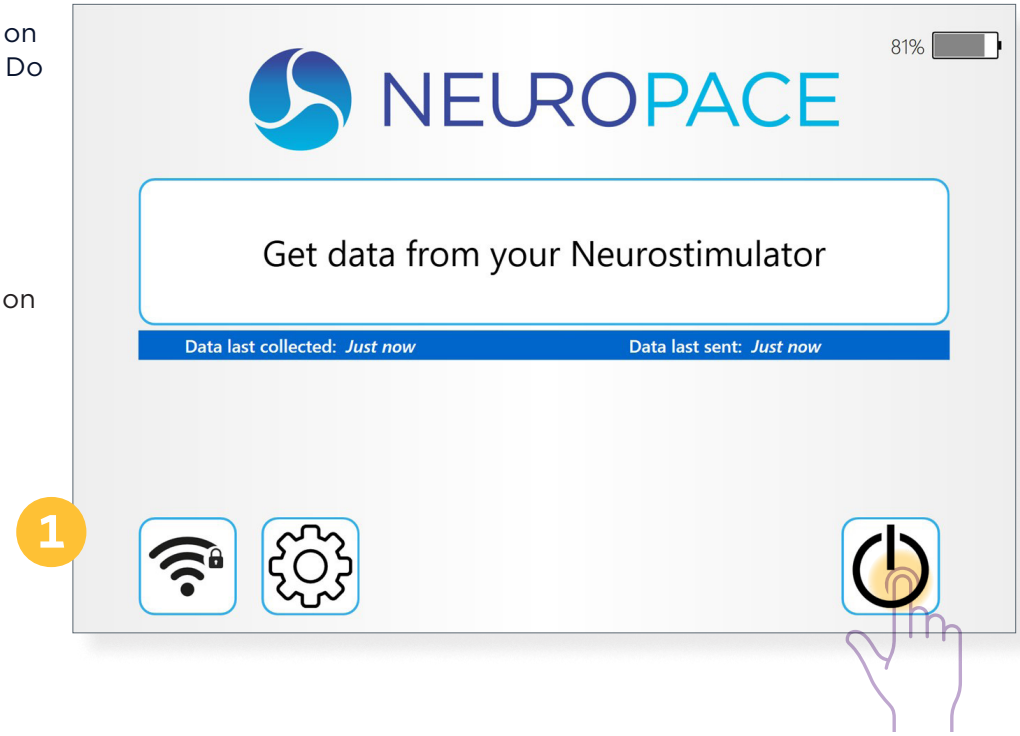


TURN OFF THE REMOTE MONITOR

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

Note: Use the Power button on screen to turn off the tablet. Do not use the hardware power button on top of the tablet except to turn it on.

1. Touch the **POWER** button at lower right on the Home screen.



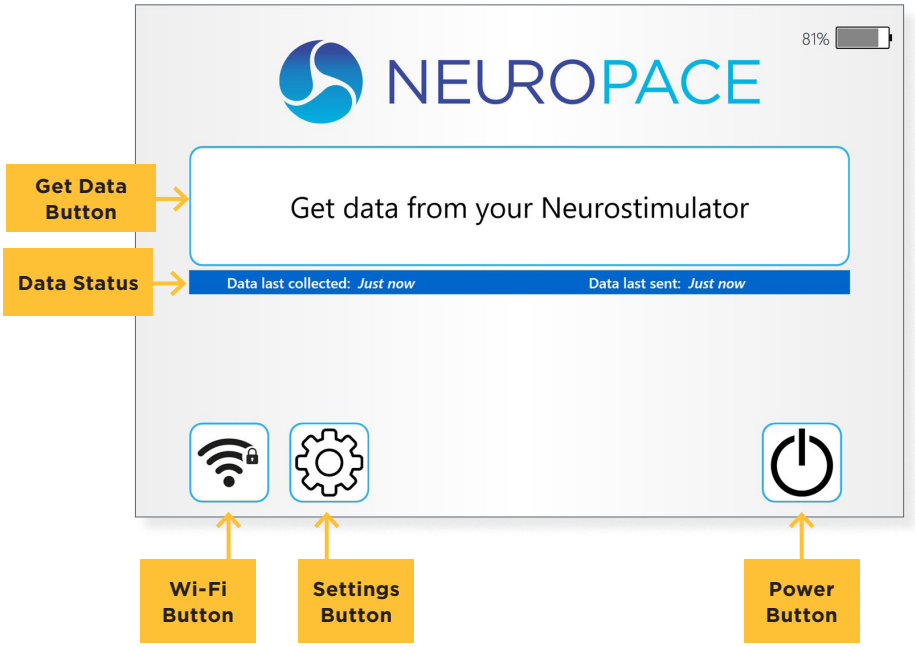
2. The **Shutdown** overlay appears. Touch the **Shutdown** button to confirm you want to turn the remote monitor off.

Get Data

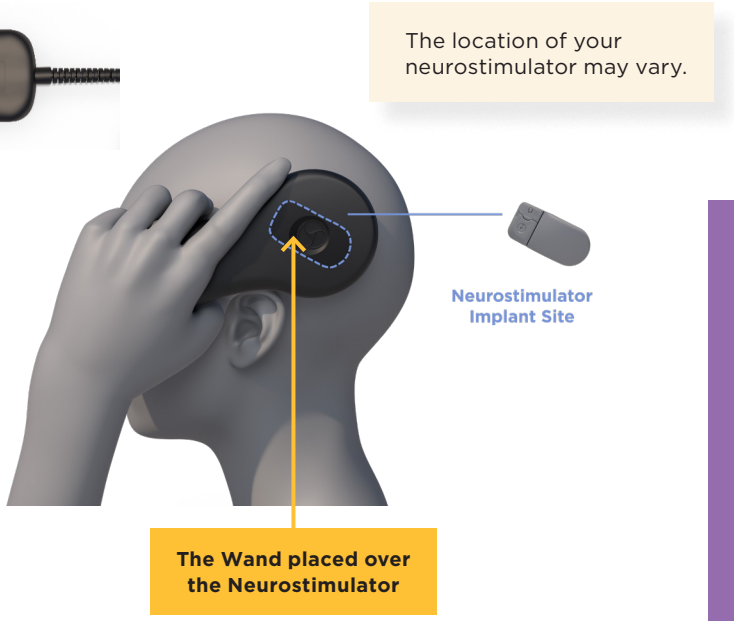
Get Data from Your Neurostimulator

When you get data from your neurostimulator, observe 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 ***Understanding Signal Level and Quality on page 42*** and ***Electromagnetic Emissions and Immunity on page 58*** for more information.

1. Turn on the remote monitor: Press the hardware power button.
After checking for software updates, the Home screen appears.



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.

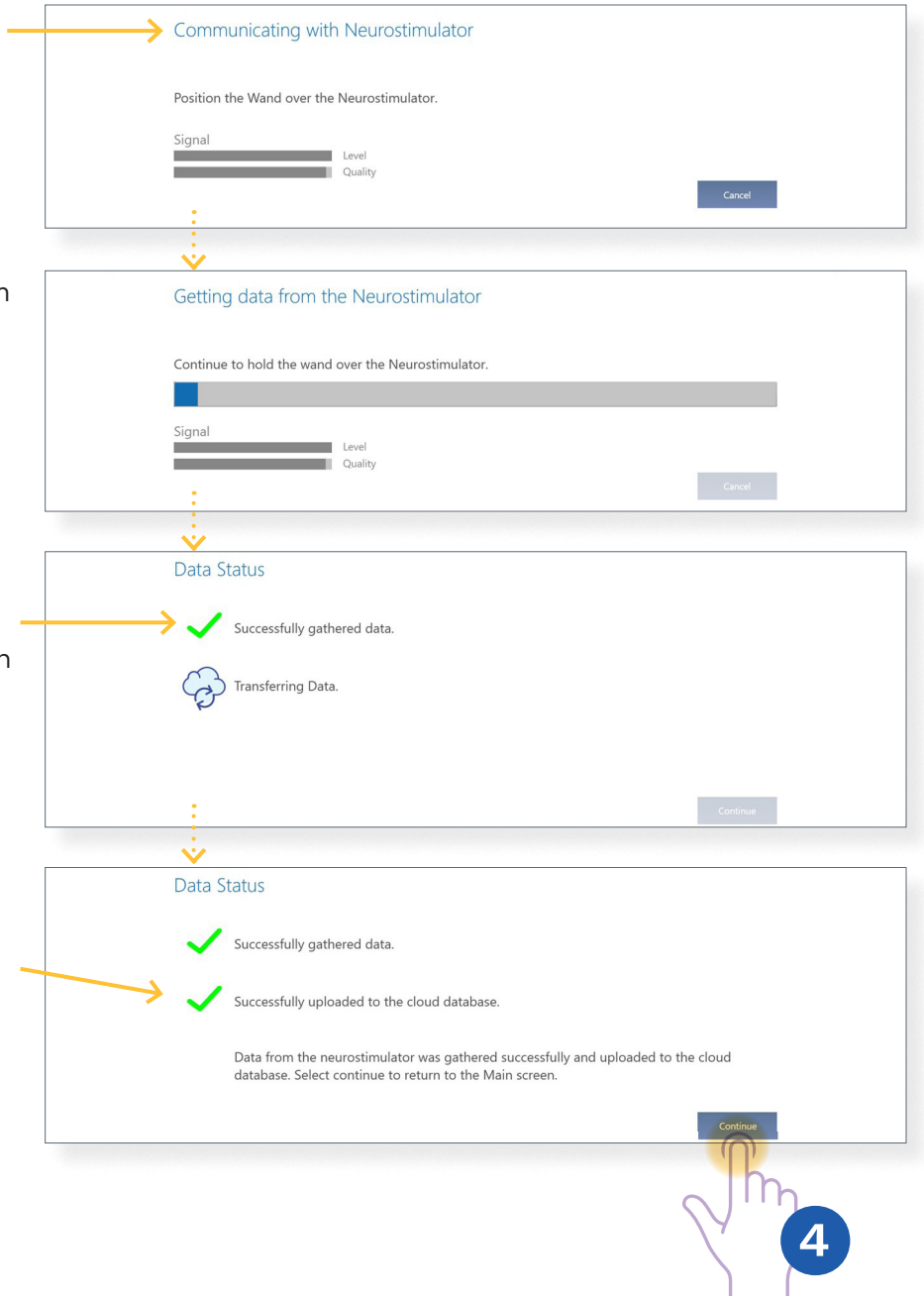


3 While holding the wand in place, touch **Get Data from your Neurostimulator** on the Home screen. The screen reports "Communicating with Neurostimulator" and then "Getting data from the Neurostimulator." If it says anything else, read and follow the on-screen instructions to complete data gathering.

4 When the screen reports "Successfully gathered data," you can put down the wand.

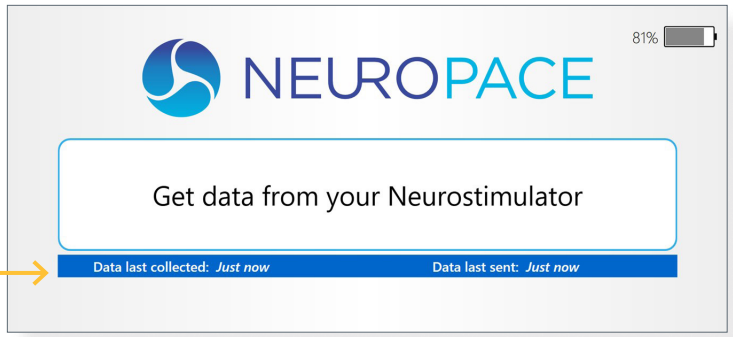
The remote monitor automatically starts transferring the data to the PDMS database, reports progress, and reports success when complete, as shown.

Select **Continue** to return to the Home screen.

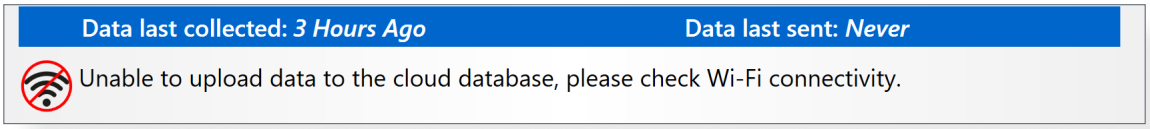


Normally it takes less than a minute to upload data, but it depends on the speed of your Wi-Fi connection. It is not necessary to monitor upload. If the device is not connected to Wi-Fi, the data will be uploaded automatically the next time it is connected. Nothing will be lost.

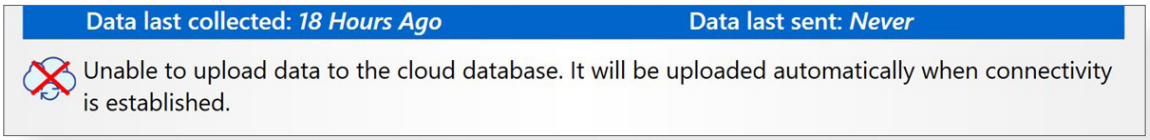
When you return to the Home screen, note that the blue bar in the middle of the screen displays the data status, which includes when the data was last collected (from the neurostimulator) and when the data was last sent (to the PDMS database). When you return, the text for both will say "Just now" if data was gathered and sent successfully.



Other messages can appear under the blue bar if there was a problem, as shown in the examples below.

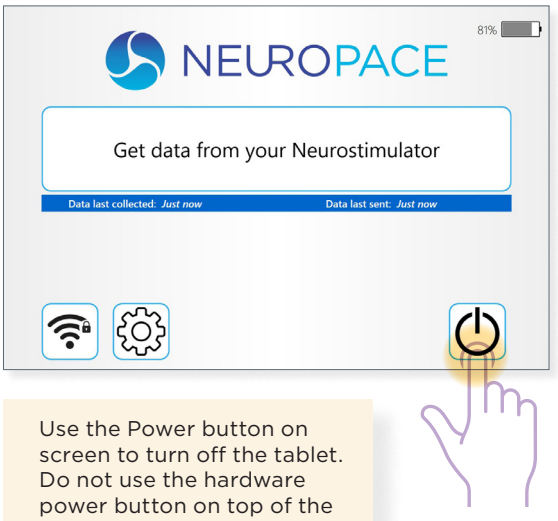


This message means that your remote monitor is not connected to Wi-Fi and you should touch the Wi Fi button at lower left to connect to an available network. Refer to ***Connect to Wi-Fi on page 32***. Once you connect to Wi-Fi, your data will be uploaded automatically.



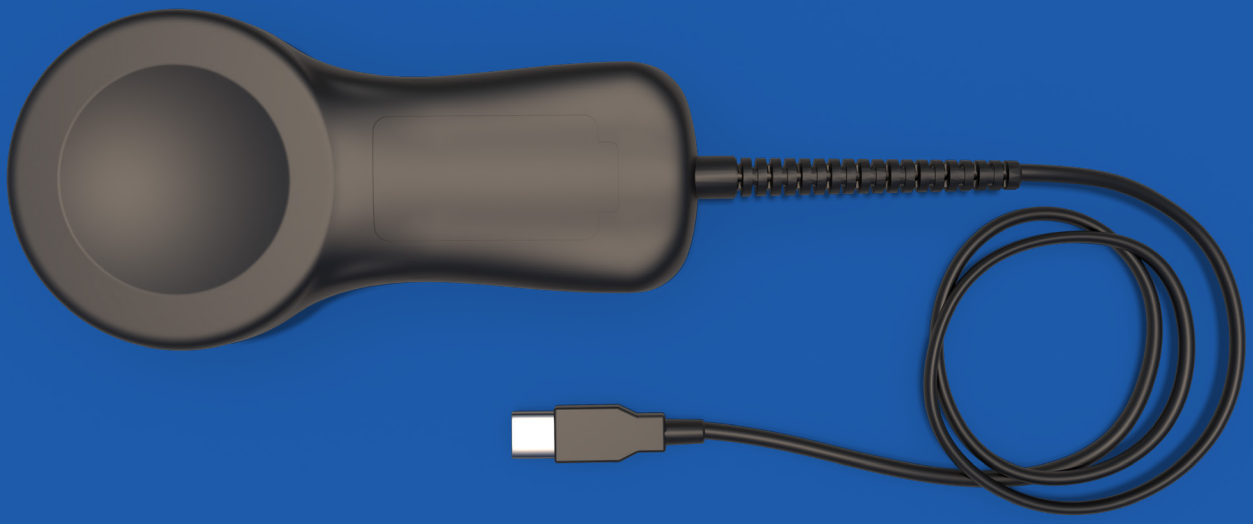
This message means the remote monitor cannot connect to the PDMS database over the Internet, even though your remote monitor is connected to Wi-Fi. This is probably due to a temporary Internet or database outage. Leave your remote monitor on, and the data will be uploaded automatically when the problem is resolved; then the message will disappear and you should turn off your remote monitor.

1. **Power off when done.** When you are finished using the remote monitor, be sure to turn it off. This will help conserve tablet battery power and electricity when not in use. Touch the **Power** button on the Home screen, then touch the **Shutdown** button to confirm you want to turn the remote monitor off.



Use the Power button on screen to turn off the tablet. Do not use the hardware power button on top of the tablet except to turn it on.

Wand Signal



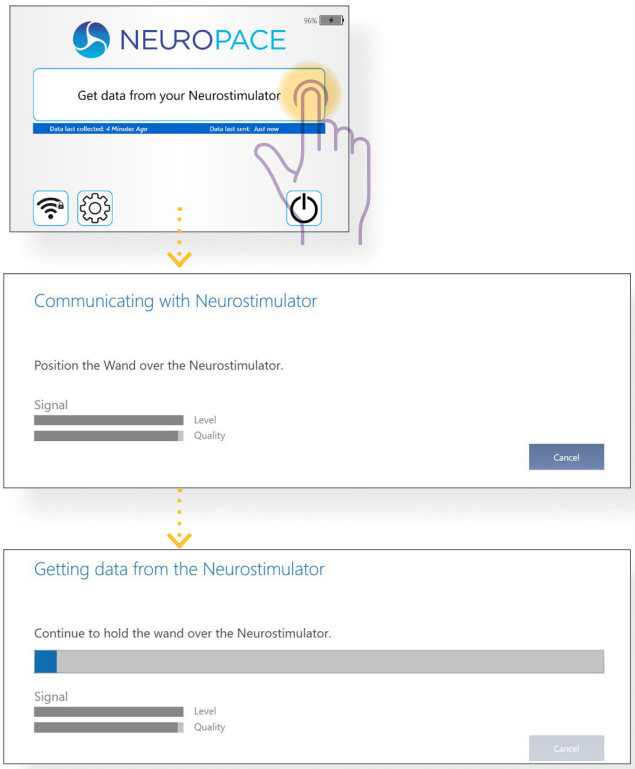
Wand Signal Basics

The wand is used to collect data from the neurostimulator and store it in the tablet. 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 tablet is plugged in to an electrical outlet. Instead, make sure the tablet battery is sufficiently charged and unplug the tablet (disconnect the power cord) before using the wand. While you get data from your neurostimulator, you can observe the level and quality of the wand signal to confirm proper placement of the wand and that there are no large sources of EMI that may affect data collection. Observe the signal level and quality in particular when:

- You first set up the remote monitor.
- You move the remote monitor to a new location.
- You have problems collecting data.
- 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 tablet is sufficiently charged and unplug it from the electrical outlet.

To check the signal level and quality, see the instructions to ***Get Data from Your Neurostimulator on page 37***.



UNDERSTANDING SIGNAL LEVEL AND QUALITY

While gathering data, the screen shows signal level and quality. The signal Level is the current signal strength between the wand and the neurostimulator. The Level will vary as you move the wand closer or further from the neurostimulator. The signal Quality is the current signal strength based on how free the signal is from interference.

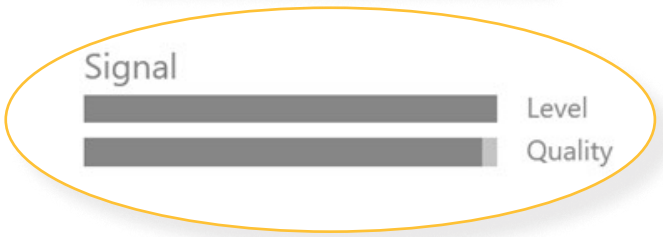
Both bars will range from empty to full, with the bars representing the level and quality of the current signal. Signal level and quality are considered “high” when the bars are at least half full. This will typically allow for data collection to occur without interruption.

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 must move away from sources of interference. To do this, you can:

- Be sure the tablet is disconnected from the electrical outlet.
- Move the remote monitor to another location.

You can observe the level and quality of the wand signal

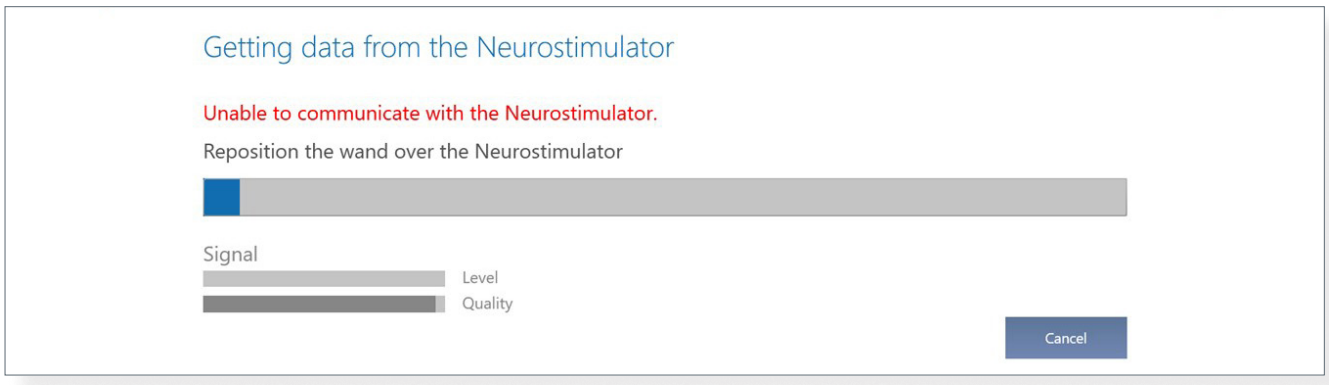


High Level, high Quality

Low Level, high Quality

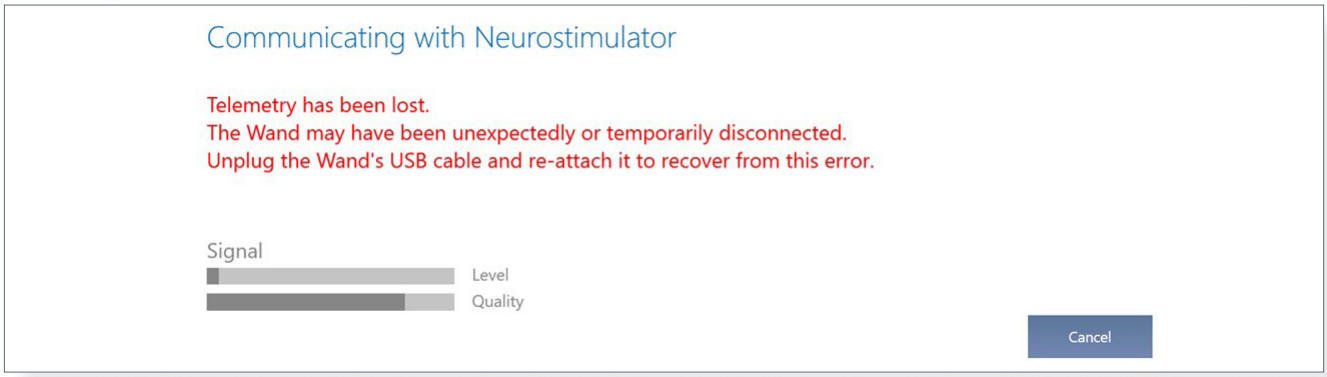
WAND TOO FAR AWAY OR WAND DISCONNECTED

If you move the wand too far away from the neurostimulator during data collection, the following message may appear: “Unable to communicate with the Neurostimulator.”



Move the wand closer to the neurostimulator until that message disappears, which means that data collection has resumed.

If the wand is disconnected during data collection, the message shown below may appear. Follow the on-screen instructions to re-attach the wand cable and resume.

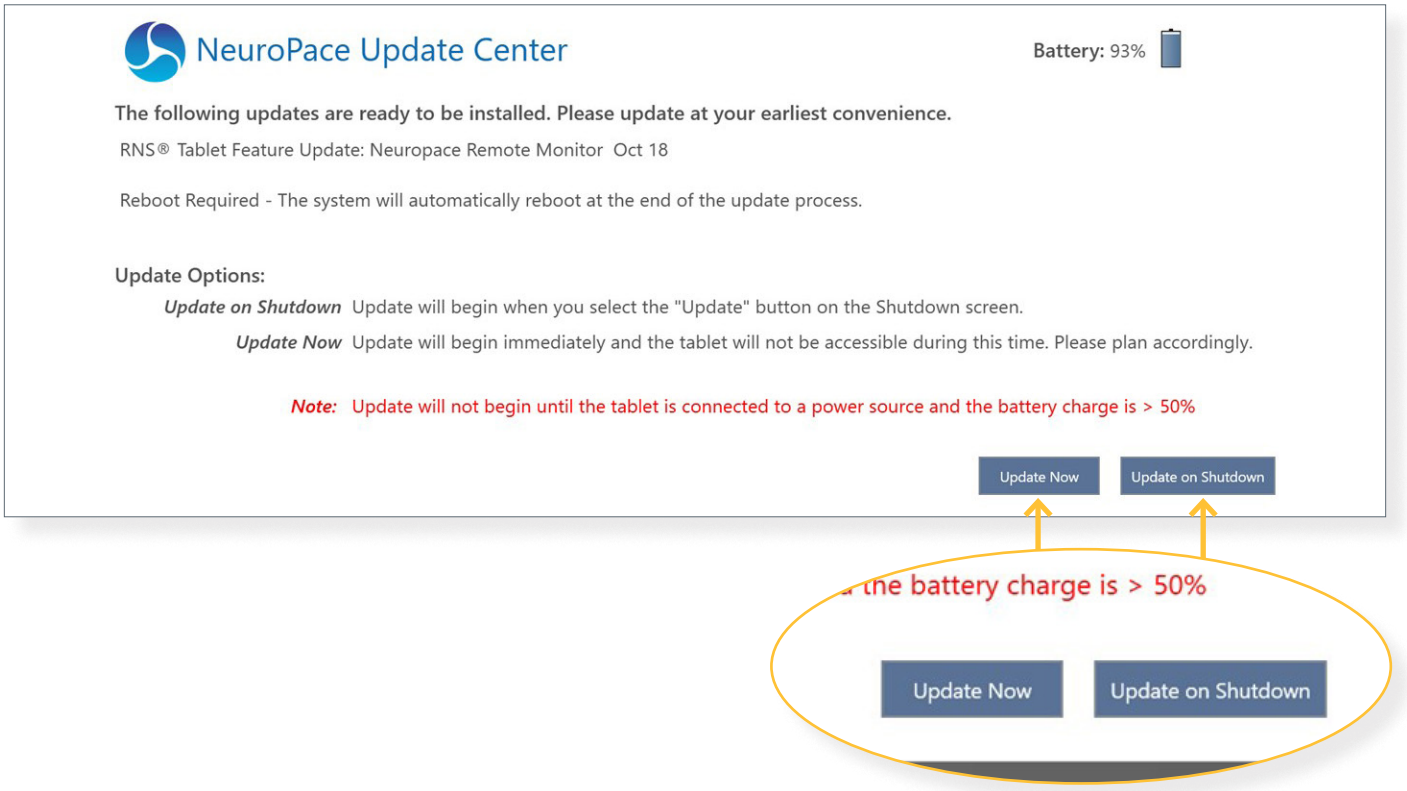


If you get another type of error message, follow the instructions on the screen and then try again. See ***Data Collection Problems on page 55*** for more information. If you still need assistance, contact NeuroPace Customer Support.

Update Center

NeuroPace Update Center

The remote monitor checks for software updates when you power on the tablet. The **NeuroPace Update Center** opens if any updates are available for installation. As described below, the Update Center identifies the update type(s) and allows you to update now or on shutdown.



UPDATE TYPES

1. **Feature Update**: These updates contain interface changes or new feature updates.
2. **Urgent Security Update**: These updates are required to address cybersecurity for the remote monitor and should be done as soon as possible. They do not include any interface changes or new features.

Note: Some updates require the tablet to restart. Under these circumstances, upon completion of the update, the system will restart automatically and open to the Home screen again.

UPDATE OPTIONS

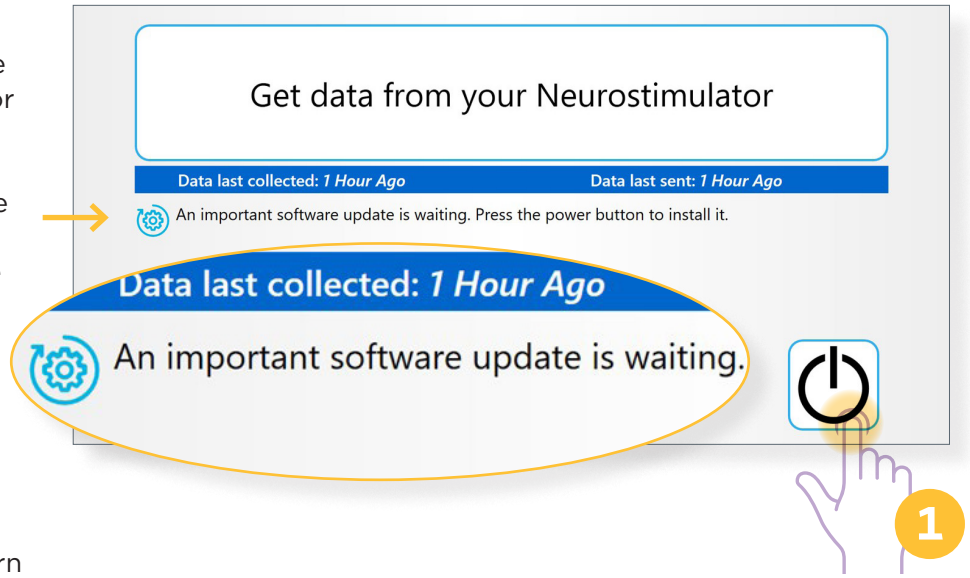
Most updates should require only a few minutes to install. NeuroPace recommends you install updates immediately. Note that once an update starts it cannot be canceled; interrupting an update by powering off the tablet can damage the tablet.

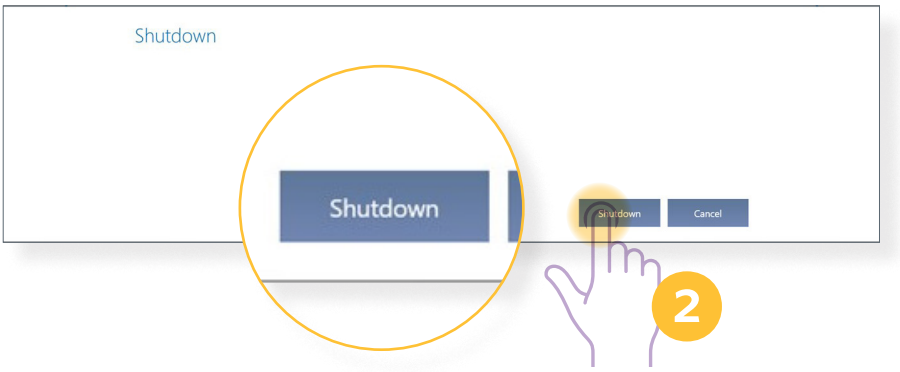
1. **UPDATE NOW:** This option starts the update immediately and the tablet will not be available during this time.
2. **UPDATE ON SHUTDOWN**: This option postpones the update until you shut down the tablet.

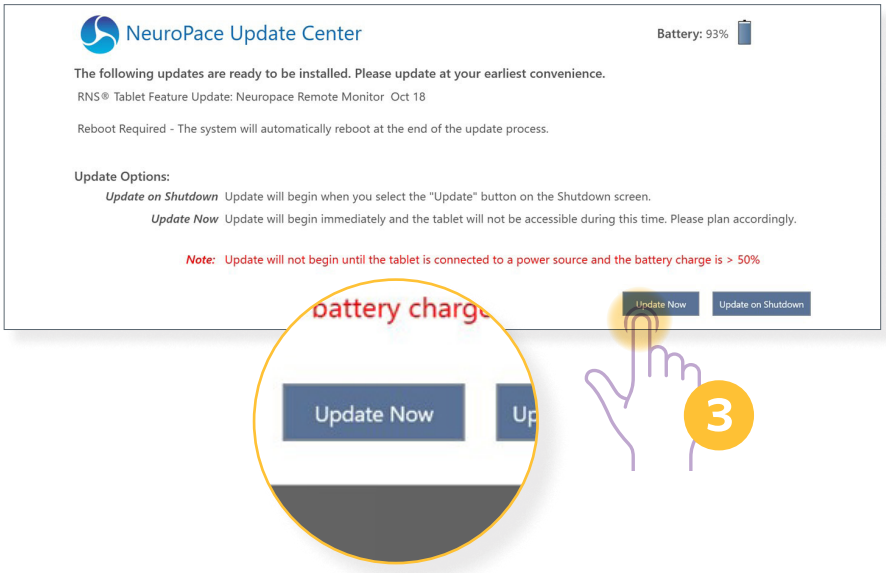
UPDATE WAITING

If an update becomes available while the tablet has been on for a while, the following message appears on the Home screen: “An important software update is waiting. Press the power button to install it.” NeuroPace recommends you follow the instructions to install it:

1. Press the power button at lower right on the Home screen.
2. Next touch the **Shutdown** button to turn off the remote monitor.
3. When you restart the tablet, the NeuroPace Update Center will appear: select **Update Now** to proceed with the update.



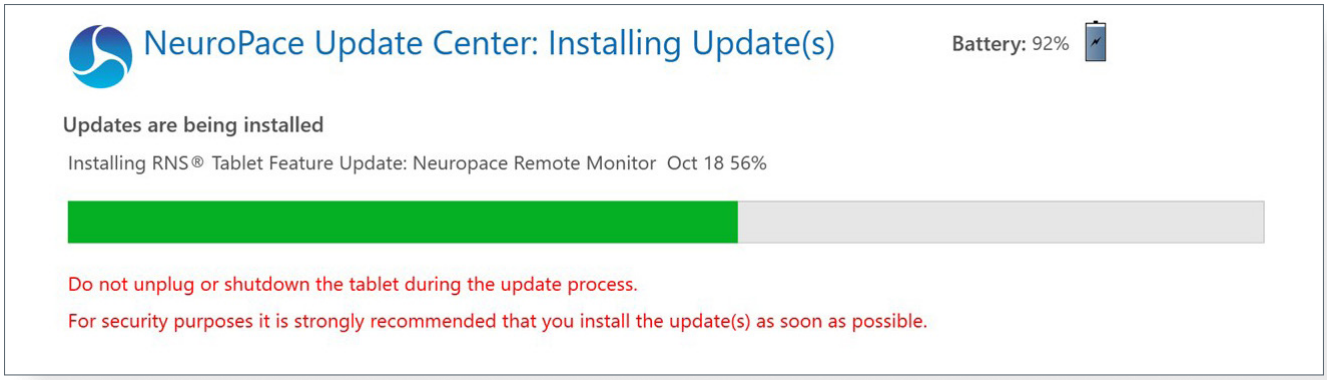




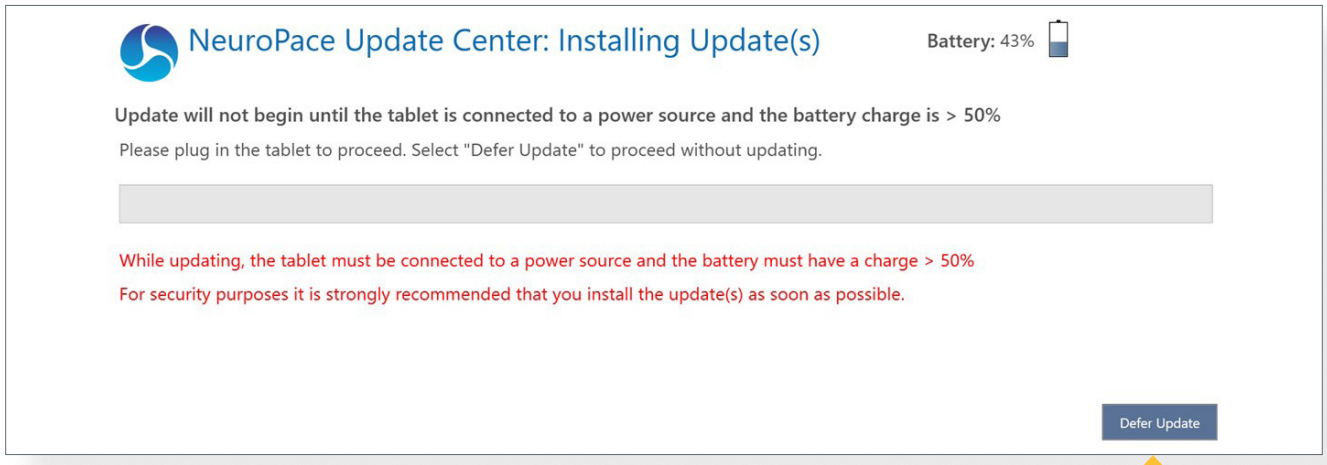
Use the Power button on screen to turn off the tablet. Do not use the hardware power button on top of the tablet except to turn it on.

UPDATE PROCESS AND POWER REQUIREMENTS

When an update begins, the screen name shows **NeuroPace Update Center: Installing Update(s)** and reports update progress.



Power requirements: Updates cannot proceed until the remote monitor tablet is connected to a power source and the battery charge is greater than 50%. These power requirements ensure that the tablet remains powered on throughout the update, so it is not interrupted. It is recommended to keep the tablet plugged in until the update completes.

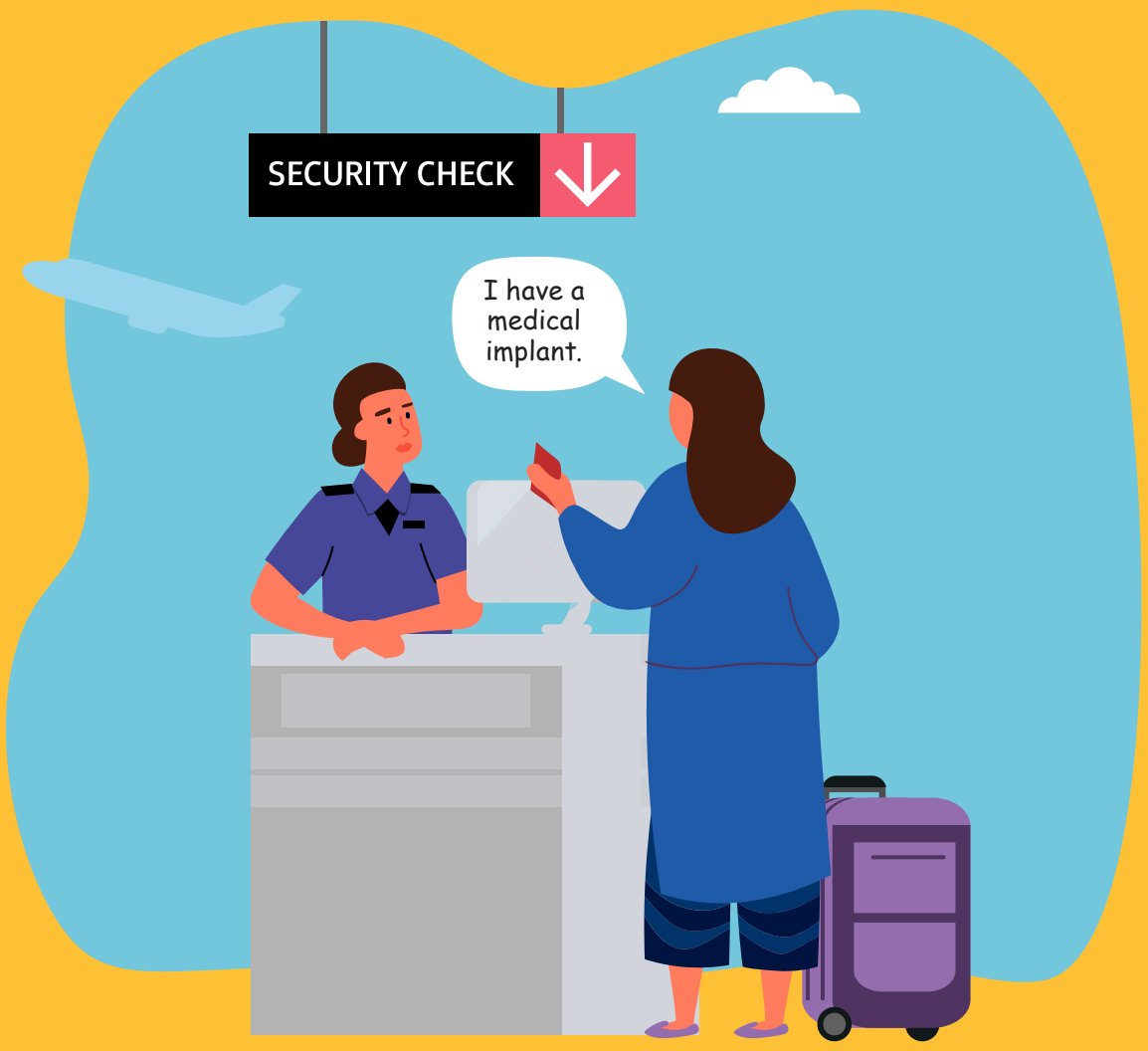


Defer Update Button

If your remote monitor is not plugged in and battery level is not above 50%, software updates will not start. Follow the instructions on screen as applicable to either plug in the tablet or wait for the battery to reach the required level. When the power requirements are met, the update will begin automatically.

If the software update has not started, you can select the option at lower right to **Defer Update** until the next time you restart the tablet, at which time the **NeuroPace Update Center** will appear again.

Travel



Traveling with the RNS® System

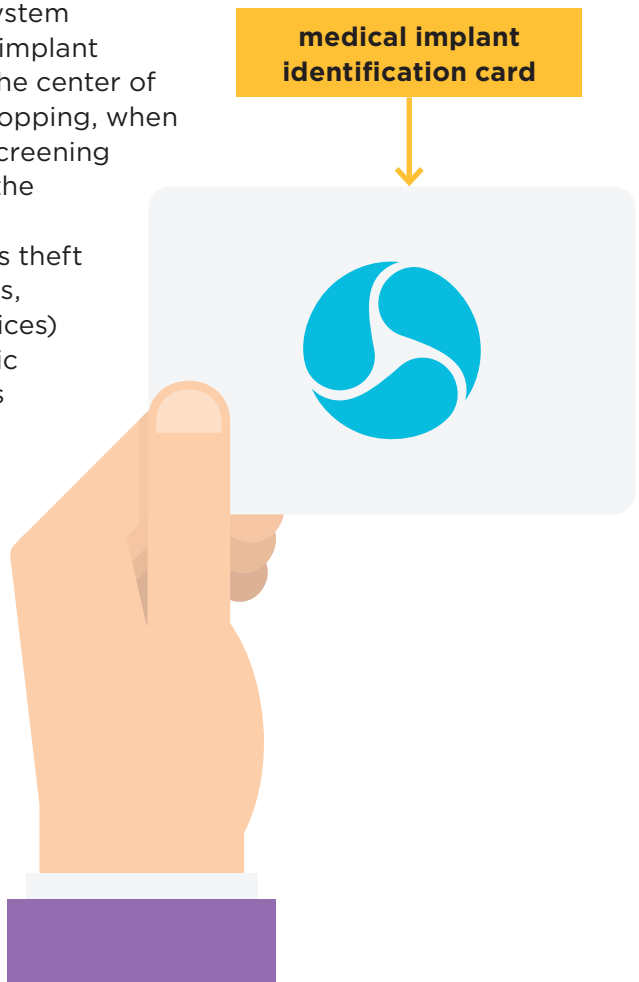
There are a few things you need to be aware of when traveling. If you plan to take the remote monitor with you, make sure to disassemble the parts and store them in the carrying case.

AIRPORT SECURITY

The remote monitor tablet can be treated like any other computer when going through airport security.

WARNING: 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, security tag deactivators, 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).



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.

TRAVELING OUTSIDE THE U.S.

The steps for connecting to the Internet from your remote monitor may be different outside the U.S. and you might not be able to connect or send data. Talk with your doctor in advance to find out what you should do in these situations.

Care and Maintenance

Care and Maintenance

NEUROSTIMULATOR AND LEADS

No special care and maintenance is required for the neurostimulator and leads.

REMOTE MONITOR AND WAND

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

- To remove dirt or dust from the wand or tablet, 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 tablet.
- When not in use, the remote monitor should be turned off.
- DO NOT store or transport the wand or tablet 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 tablet.
- The tablet has a rechargeable battery installed. Battery power will last at least 2 hours on a full charge. The battery recharges any time the tablet is plugged into an outlet but it could take about 2 hours to fully charge a drained battery. Make sure the battery is adequately charged before you collect data with the tablet.
- If you need to move the remote monitor to another location, first disassemble the pieces and store them in the carrying case.
- DO NOT cover or enclose the tablet with anything that could restrict airflow and not allow heat to disperse. All tablet computers generate a moderate amount of heat when they are turned on. Restricting the airflow can damage the tablet.
- 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 tablet. If the tablet does not respond after a shock, refer to

  Tablet Does Not Respond on page 53
  for instructions on how to restart the tablet when it does not respond.

RETURN / DISPOSAL OF TABLET COMPUTER AND WAND

The tablet 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.

Troubleshooting

Remote Monitor Problems

REMOTE MONITOR PROBLEMS	
Remote Monitor Does Not Turn On	
Problem	The remote monitor does not turn on when the power button is pressed.
Possible Cause	Tablet 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 tablet battery for power, make sure it is fully charged. The tablet must be connected to an outlet for at least 2 hours for the battery to be fully charged.

REMOTE MONITOR PROBLEMS	
Tablet Battery Power Does Not Last	
Problem	When fully charged the tablet battery power lasts less than 1 hour.
Possible Cause	The tablet battery can no longer hold a charge.
What to Do	Contact NeuroPace Customer Support to arrange for a replacement remote monitor.

REMOTE MONITOR PROBLEMS	
Tablet Does Not Respond	
Problem	The tablet does not respond to touches.
Possible Cause	There may be a problem with the tablet operating system.
What to Do	Press and hold the power switch on top of the tablet for at least 5 seconds until the tablet turns off. (A brief press may put the tablet in “sleep” mode with a blank screen.) Restart the tablet by pressing the power switch. If the problem persists, contact NeuroPace Customer Support for assistance.

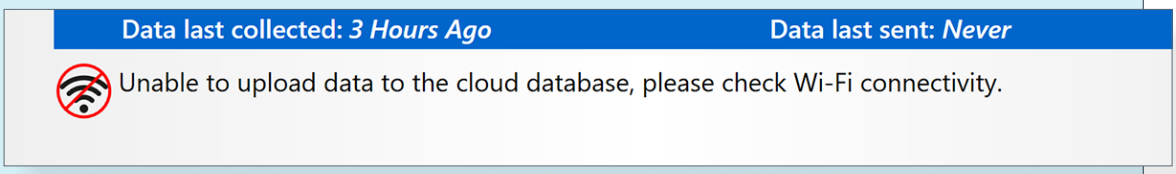
Wand Problems

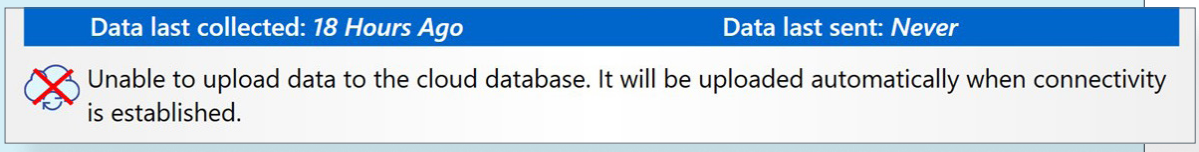
WAND PROBLEMS	
Low Signal Strength	
Problem	The wand signal strength is very low, absent or the signal is inconsistent.
Possible Causes	• The wand may be loosely connected, disconnected from the tablet or plugged into the wrong port. • The wand is not positioned properly over the neurostimulator. • The 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 tablet and you have positioned the cupped side of the wand directly over the neurostimulator. • Follow the steps to ***Get Data from Your Neurostimulator on page 37*** and observe the signal level and quality bars. Refer to ***Understanding Signal Level and Quality on page 42***. If the signal level is low or bouncing up and down, hold 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 tablet from the electrical outlet, if it is plugged in. Make sure the battery is charged before doing so. If this does not solve the problem, try moving the remote monitor to another location away from other electronic devices, and then try again to get data and observe the wand signal. • If your wand signal continues to be a problem, contact NeuroPace Customer Support for assistance.

Data Collection Problems

DATA COLLECTION PROBLEMS	
Problems Getting Data	
Problem	One of the following messages appears on the screen: • "Unable to communicate with the neurostimulator. Reposition the wand over the Neurostimulator." • "Telemetry has been lost. The Wand may have been unexpectedly or temporarily disconnected. Unplug the Wand's USB cable and re-attach it to recover from this error."
Possible Causes	• The wand was moved while collecting data from the neurostimulator. • The wand cord may be loosely connected or disconnected from the tablet USB port. • There is interference from a nearby electronic device.
What to Do	• Follow the on-screen instructions. • 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. • Make sure the wand is properly connected to the tablet. • If the signal quality is low, a nearby electronic device (e.g., another computer, television, microwave, etc.) may be causing interference, or there may be interference if the remote monitor power cord is plugged into an electrical outlet. If it is plugged in, make sure the battery is charged adequately and then disconnect from power. If this does not solve the problem, try moving the remote monitor to another location and then try again to get data and observe the wand signal.

Problems Uploading Data

Problems Uploading Data	
Not Connected to Wi-Fi or Wi-Fi Turned Off	
Problem	The following message appears on the Home screen: 
Possible Causes	• Your remote monitor is not connected to Wi-Fi. • The Wi-Fi on your remote monitor is turned off. • Your Internet router or gateway has a problem.
What to Do	• Touch the Wi Fi button at lower left of the Home screen. • If Wi-Fi is turned off (the On/Off button is at upper right of the Wireless Network Connection screen), then turn it back on. It should be left on. Proceed to the next step. • Select an available network and touch **Connect** and enter the Wi-Fi password if required. Refer to ***Connect to Wi-Fi on page 32*** for details. Once you connect to Wi-Fi, your data will be uploaded automatically. • If the previous steps do not resolve the problem, check that your Internet router or gateway is turned on and its cables are properly connected.
What to Do	• Touch the Wi Fi button at lower left of the Home screen. • If Wi-Fi is turned off (the On/Off button is at upper right of the Wireless Network Connection screen), then turn it back on. It should be left on. Proceed to the next step. • Select an available network and touch **Connect** and enter the Wi-Fi password if required. Refer to ***Connect to Wi-Fi on page 32*** for details. Once you connect to Wi-Fi, your data will be uploaded automatically. • If the previous steps do not resolve the problem, check that your Internet router or gateway is turned on and its cables are properly connected.

Problems Uploading Data	
Not Connecting to the PDMS Database	
Problem	The following message appears on the Home screen: 
Possible Causes	• There is an unknown problem connecting to the NeuroPace PDMS database through the Internet, even though your remote monitor is connected to Wi-Fi. There could be a temporary disruption to the Internet, or the NeuroPace database server could be down temporarily. • Internet service to your Internet router or gateway is down. • The Wi-Fi network requires you to enter information in a web browser to connect to the Internet, as at some hotels and other businesses. In this case, the remote monitor indicates you are connected to the Wi-Fi network, but you cannot complete connection to the Internet because the remote monitor does not provide a web browser. You must select another Wi-Fi network to upload your data to the PDMS.
What to Do	• Check with your Internet service provider to see if there are outages in your area or other issues that may affect Internet access. • If you have Internet service, the problem is likely with the NeuroPace database server. Such problems are temporary, and when the problem is resolved, data will be uploaded automatically and the message will disappear. • If the Wi-Fi network requires you to enter information in a web browser to connect to the Internet, as at some hotels and other businesses, select another Wi-Fi network to upload your data to the PDMS.

Problems Uploading Data	
Sending Data Takes a Long Time	
Problem	Sending data to the PDMS database is taking a long time.
Possible Causes	• There may be a problem with the PDMS database server or with your Internet connection. • A large amount of data is being sent to the PDMS database.
What to Do	• Always allow up to 5 minutes for data to be sent. • Check with your Internet Service Provider to see if there are outages in your area or other issues that may affect Internet access.

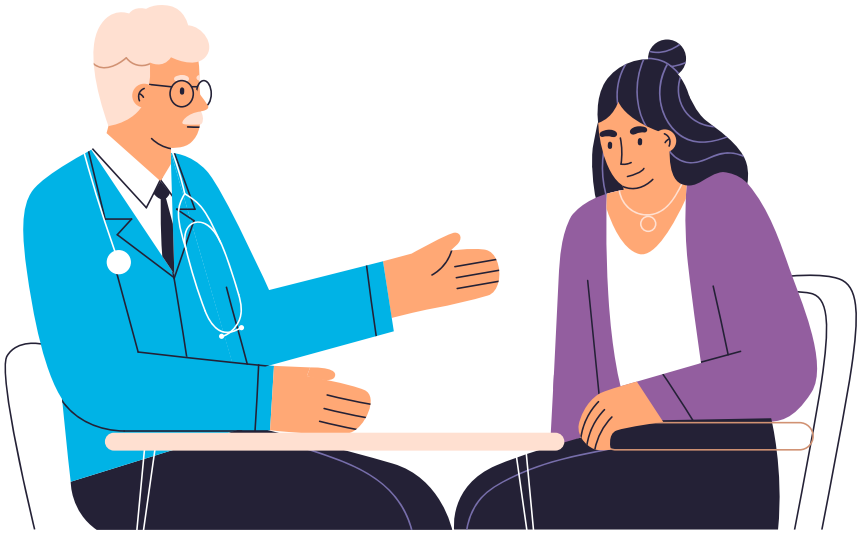
Electromagnetic Emissions and Immunity

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 EMI on ***page 8*** 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.

POTENTIAL EMI SOURCES	
Item or procedure	**Contraindicated**
Diathermy treatment	●
Electroconvulsive therapy	●
Transcranial magnetic stimulation	●

You must consult your doctor to determine whether an MRI scan is possible for you, even if you have had an RNS neurostimulator explanted. Refer to ***WARNING: MRI Safety Information on page 6*** for more information.



HOSPITAL OR MEDICAL ENVIRONMENTS

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

- **Should not affect operation:** Commonly used items that should not affect the operation of the neurostimulator.
- **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.

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 ***Safety Information on page 4*** for specific information.

Item or procedure	Should not affect operation	Avoid or exercise caution	Notes
Computerized tomography (CT or CAT) scans		●	See warning, ***page 6***
Diagnostic ultrasound	●		
Diagnostic X-ray	●		
Electrolysis		●	See warning, ***page 6***
Implanted cardiac devices		●	See warning, ***page 6***
Lithotripsy		●	See warning, ***page 6***
Medical procedures and dental work		●	See caution, ***page 9***
Other active implanted medical devices		●	See caution, ***page 10***
Radiation therapy		●	See warning, ***page 6***
Removal and EMI considerations		●	See caution, ***page 10***

HOME, WORK, OR PUBLIC ENVIRONMENTS			
Item or procedure	**Should not affect operation**	**Avoid or exercise caution**	**Note**
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	🟢		
Body fat measurement scales		🔴	
Cell phones and Bluetooth devices	🟢		
Electric arc welding equipment		🔴	
Electric blankets and heating pads	🟢		
Electric fences		🔴	
Electric induction heaters		🔴	
Electric steel furnaces		🔴	
Electric substations, power generators, and large transformers		🔴	
Electric toothbrushes, electric shavers, and hair trimmers	🟢		
Household magnets and magnetic bracelets		🔴	See caution, ***page 9***
Jackhammers		🔴	
Microwave ovens	🟢		
Personal computers, electric typewriters, copiers, and fax machines	🟢		
Portable and mobile RF communications equipment		🔴	See warning, ***page 8***
Power lines and transmission towers		🔴	
Radiofrequency identification (RFID) sources		🔴	See warning, ***page 8***
Stun guns		🔴	
Televisions, AM/FM radios, stereos, personal music players	🟢		
Vacuum cleaners and electric brooms	🟢		

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:

- RNS® Neurostimulator, models RNS-300M and RNS-320.
- RNS® Tablet, model 5000.
- Wand, model W-02.
- Remote Monitor, models DTR-300, DTR-300-E, 5100, and 5106.

The devices comply with IEC 60601-1-2:2020, ISO 14708-3, and FCC 47 CFR Parts 2 and 15.

- Portable and mobile RF communications equipment can affect the devices.
- 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 remote monitor with wand is designed for use in the home by a patient. 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.

Note: Unless otherwise indicated in the table footnotes, emissions testing information in the tables below apply to all of the devices addressed in this section as listed above.

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 6 GHz	
Harmonic emissions (IEC 61000-3-2)	Class A Device[1]	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[1]	

[1] Tablet (model 5000) and Remote Monitor (models 5100, 5106) with Wand (model W-02) tested for harmonic emissions and flicker. Other products excluded from harmonic emissions and flicker testing.

TABLE 2: GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR ALL EQUIPMENT AND SYSTEMS		
Immunity test	**Compliance**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact discharge[1] ± 2, 4, 8, 15 kV air discharge[1]	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	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[3]	
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[4] 40% UT 5 cycles[4] 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.
Power Frequency Magnetic immunity (IEC 61000-4-8)	30[5] A/m	

[1] Immunity to ESD tested to ±8 kV contact and ±15 kV air with Tablet (model 5000), Remote Monitor (models 5100, 5106) and Wand (model W-02).

[2] Immunity to electrical fast transients tested with Tablet (model 5000) and Remote Monitor (models 5100, 5106).

[3] Immunity to surge line to earth tested with Programmer (model PGM-300), Remote Monitor (models DTR-300-E, 5106).

[4] Immunity to voltage dips with compliance to 0% UT 1 cycle for Tablet (model 5000), Remote Monitor (models 5100, 5106) and to 40% UT 5 cycle for Programmer (model PGM-300) and Remote Monitor (model DTR-300-E).

[5] Power frequency magnetic immunity tested with Tablet (model 5000), Remote Monitor (models 5100, 5106) and 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[1] 6 Vrms Amateur bands	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[2, 3] d = 1.17√P (80 MHz to 800MHz) d = 2.33√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[4], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated Immunity (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz[5]	
Proximity field from RF Wireless Communications Equipment (IEC 61000-4-3)	See table in footnote	
Proximity magnetic fields (IEC 61000-4-39)[6]	8 A/m, 30kHz 65 A/m, 134.2 kHz 2.1 kHz PM 7.5 A/m, 13.56 MHz 50 kHz PM	

[1] Conducted immunity of the Tablet (model 5000) and Remote Monitor (models 5100, 5106 compliant to 6 Vrms in the ISM bands. Wand (model W-02) is compliant to 6 Vrms in the ISM and Amateur bands.

[2] 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.

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

[4] 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.

[5] Radiated immunity of the Programmer (model PGM-300), Remote Monitor (model DTR-300-E) compliant to 3 V/m up to 2.7 GHz. Tablet (model 5000), Remote Monitor (models 5100, 5106) and Wand (model W-02) compliant to 10 V/m 80 MHz to 2.7 GHz and spot frequencies with pulse modulation.

[6] Proximity magnetic field immunity tested with Wand (model W-02).

TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM + 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5 500				
5 785				

TABLE 4: RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE RNS® SYSTEM[1, 2, 3]			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d = 1.17√P	**80 MHz to 800 MHz d = 1.17√P**	**800 MHz to 2.5 GHz d = 2.33√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

[1] 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.

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

[3] 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.

Clinical Studies: Risks and Benefits

Note: There are risks and benefits associated with all medical devices and treatments. Talk to your doctor about the risks and benefits of the RNS® System and whether it is appropriate for you. Your doctor can also answer questions regarding the information in this manual.

The risks and benefits of the RNS® System were measured in three clinical studies. Patients participating in the studies were all adults who had partial onset seizures that began from 1 or 2 foci in the brain, and had frequent seizures that had not been controlled with at least 2 different antiepileptic medications. The first study was designed to show safety in 65 epilepsy patients who were being treated with the RNS® System for 2 years. The second study was designed to measure both the risks and benefits in 191 epilepsy patients being treated with the RNS® System and followed for 2 years. Following completion of one of the first two studies, patients had the option to enroll in the third long-term follow up study. During the third study, patients continued to receive stimulation and were followed for an additional 7 years to monitor long-term risks and benefits. Patients are still being followed in this long-term follow-up study. The first two clinical studies have been completed.

All of the studies looked at the risks of the RNS® System by measuring the number of adverse events. Adverse events included any complication or complaint that arose during the studies. Adverse events were measured for all patients throughout all of the studies.

In order to understand the benefits of the RNS® System, the second study had a 3 month comparison period. During the comparison period, half of the patients received stimulation (Treatment Group) and the other half did not (Control Group). Following the comparison period, all patients were able to receive stimulation for the rest of the time in the study. The studies measured benefits by looking at whether patients being treated with stimulation had fewer seizures. Patients completed daily seizure diaries and also filled out questionnaires about their seizure severity and quality of life.

Risks

SAFETY RESULTS

You can ask your doctor to discuss adverse events reported during the studies. Safety was assessed in all patients implanted with the RNS® System in all of the studies. Any event that occurred while a patient was participating in one of the studies at any time was reported as an adverse event, whether the doctor thought it was related to the RNS® System or not. This is customary in studies of new treatments.

In addition to reporting every adverse event, the investigator classified each adverse event as serious or non-serious and as device-related (which includes device-related and device relation uncertain) or not device-related. Adverse events were considered serious if they resulted in:

- Significant risk or impact on health
- Serious injury or death
- Hospital admission
- Surgery to stop or lessen the event

PIVOTAL STUDY

Serious Adverse Events Following Surgery (Pivotal Study)

The main goal of the Pivotal study was to compare the safety of the RNS® System to the safety of epilepsy surgery and to the safety of Deep Brain Stimulation for movement disorders. From implant to 4 weeks, the rate of serious adverse events with the RNS® System was 12.0% compared to 15% for epilepsy surgery. From implant to 12 weeks, the rate of serious adverse events was 18.3% for the RNS® System compared to 36% for the Deep Brain Stimulator. These results show that the safety of the RNS® System is comparable to these other procedures.

ADVERSE EVENTS DURING THE COMPARISON PERIOD (PIVOTAL STUDY)

Serious adverse events were compared for the patients who were receiving stimulation during the Comparison Period (the Treatment Group) and for those who were not (the Control Group). There were 4 patients in the Treatment group (4.2%) and 5 in the Control Group (5.4%) who had serious adverse events. Table 1 on page 19 presents the serious adverse events that occurred in these 9 patients.

During this same time period, non-serious adverse events occurred in 70 Treatment Group patients (72.9%) and 62 Control Group patients (66.7%). Table 2 on page 20 lists the non-serious adverse events reported in 2.5% or more of the patients in either the Treatment or the Control Groups. This includes all adverse events whether the investigator felt they were device-related or not.

TABLE 1: PIVOTAL STUDY - SERIOUS ADVERSE EVENTS DURING THE COMPARISON PERIOD

Adverse Event	Treatment (N=96)	Control (N=93)
	% (#) patients with events	% (#) patients with events
Complex partial seizure increased	1.0% (1)	1.1% (1)
Alcohol poisoning	1.0% (1)	--
Hernia (hernia surgery)	--	1.1% (1)
Implant site infection due to seizure	--	1.1% (1)
Jaw fracture due to seizure	--	1.1% (1)
Myocardial infarction (heart attack)	1.0% (1)	--
Nephrolithiasis (kidney stone)	--	1.1% (1)
Pneumonia	1.0% (1)	--
Simple partial seizures (sensory)	--	1.1% (1)
Simple partial seizures increased (sensory)	--	1.1% (1)

TABLE 2: PIVOTAL STUDY - SERIOUS AND NON-SERIOUS ADVERSE EVENTS IN ≥2.5% OF PATIENTS IN EITHER GROUP DURING THE COMPARISON PERIOD		
Adverse Event	**Treatment (N=96)**	**Control (N=93)**
	% (#) patients with events	% (#) patients with events
Nasopharyngitis (sore throat and runny nose)	6.3% (6)	8.6% (8)
Headache	5.2% (5)	7.5% (7)
Contusion due to seizure (bruise)	7.3% (7)	2.2% (2)
Skin laceration due to seizure (cut)	6.3% (6)	3.2% (3)
Complex partial seizures increased	4.2% (4)	3.2% (3)
Depression	5.2% (5)	2.2% (2)
Dysesthesia (painful sensation on the skin)	2.1% (2)	5.4% (5)
Influenza (flu)	4.2% (4)	3.2% (3)
Vomiting	3.1% (3)	3.2% (3)
Adverse drug reaction (bad reaction to medication)	3.1% (3)	2.2% (2)
Therapeutic agent toxicity (side effect of antiepileptic medications)	--	5.4% (5)
Upper respiratory tract infection (common cold)	1.0% (1)	4.3% (4)
Pain of skin	4.2% (4)	--
Pharyngitis (sore throat)	1.0% (1)	3.2% (3)
Abdominal pain	3.1% (3)	--
Balance disorder	--	3.2% (3)
Head injury	--	3.2% (3)

COMBINED RNS® SYSTEM STUDIES

For the combined studies, all of the adverse events that occurred to any patient at any time were collected whether the doctor thought they were related to the RNS® System or not. Over the 903 patient years of experience, 64.5% (165/256) of the patients experienced a serious adverse event and 99.2% (254/256) of the patients experienced a non-serious adverse event, including common and expected illnesses and conditions, such as colds and flus. There were no unanticipated device-related serious adverse events in any of the RNS® System studies. Further detail is provided below.

DEATHS AND SUDEP ANALYSIS (COMBINED STUDIES)

Sudden unexpected death in epilepsy (SUDEP) is a term used when a person with epilepsy suddenly dies without a clear cause of death. The actual cause of SUDEP is unknown. There was a special committee of doctors who decided whether a death was because of SUDEP.

The information about deaths covers a longer period of time than for the other safety information. As of October 24, 2012, with over 1,195 patient years of treatment, 11 of the 256 patients in the RNS® System studies had died. One patient died of a cancer (lymphoma), one patient died of complications from status epilepticus (a seizure that lasts more than 30 minutes), 2 patients died by suicide and 7 deaths were linked to possible, probable or definite SUDEP. The number of SUDEP deaths that occurred during the RNS® System studies is comparable to what is expected in patients with severe epilepsy.

DEVICE-RELATED SERIOUS ADVERSE EVENTS BY YEAR (COMBINED STUDIES)

Over the 903 patient years of experience, the most frequent device-related serious adverse events (occurring in ≥ 2.5% of patients) were implant site infection (5.9%), premature battery depletion (which required a surgical procedure) (4.3%), medical device removal (3.5%), and device lead damage (2.7%).

SERIOUS ADVERSE EVENTS OF PARTICULAR RELEVANCE (COMBINED STUDIES)

Serious adverse events of particular relevance in persons with epilepsy and in persons with an implanted medical device include intracranial hemorrhage, infection, psychiatric events, change in seizures, status epilepticus and seizure-related injury. Serious adverse events in these categories for all patients in all RNS® System studies are discussed below.

INTRACRANIAL HEMORRHAGE

Serious adverse events related to intracranial hemorrhage (bleeding in the brain or under the skull) occurred in 12 of the 256 implanted patients (4.7%):

- 4 were in the first 4 weeks after surgery.
- 3 were later than the first 4 weeks of surgery.
- 5 were due to a seizure-related head trauma.

2 patients (0.8%) had 2 non-serious adverse events because of an intracranial hemorrhage. These two events were considered non-serious because no medical treatment was required.

INFECTION

Serious adverse events related to infections near the neurostimulator occurred in 18 of the 256 patients (7.0%):

- 1 was diagnosed before the RNS® System was implanted.
- 2 were due to seizure-related head trauma.

11 of the 18 (4.3%) patients had the neurostimulator and/or leads removed because of infection.

10 patients (3.9%) had 11 non-serious adverse events because of an infection. These were infections near the neurostimulator (5 patients, 2.0%) and at the incision site (6 patients, 2.3%).

PSYCHIATRIC ISSUES

Many patients in these studies had a history of depression (49%) and/or suicidality (5.2%). Twenty-one of the 256 patients had a serious adverse event related to a psychiatric issue.

- 12 patients (4.7%) had 18 serious adverse events because of suicidality:

- Suicide (2), depression with suicidal thoughts (6), suicide attempt (6), suicidal ideation (thoughts)(2) and suicidal behavior (threats or gestures) (2).
- 3 patients had a chronic psychosis.
- 2 patients had an acute psychosis.
- 2 patients had a conversion disorder (psychogenic seizures).
- 1 patient each had depression, psychosis after a seizure, emotional distress, affect lability (mood swings), agitation, alcohol abuse and alcohol withdrawal, and an episode of a visual hallucination.

81 patients (31.6%) had 148 non-serious adverse events because of a psychiatric issue. The most common were depression (47 patients, 18.4%), anxiety (21 patients, 8.2%) and depression with suicidal thoughts (4 patients, 1.6%).

CHANGES IN SEIZURES

Some patients reported a serious adverse event because of more frequent seizures.

- 4 patients (1.6%) had more frequent simple partial motor seizures.
- 16 patients (6.3%) had more frequent complex partial seizure frequency.
- 15 patients (5.9%) had more frequent generalized tonic-clonic seizures.

Some patients reported a serious adverse event because of more severe seizures.

- 1 patient (0.4%) had more severe simple partial motor seizures.
- 15 patients (2.0%) had more severe complex partial seizure frequency.
- 11 patients (4.3%) had more severe generalized tonic-clonic seizures.
- Three patients had a serious adverse event because of a new type (new symptoms) of a seizure.

Most of these were considered serious because the patient was admitted for video-EEG monitoring or hospitalized to modify antiepileptic medications.

109 patients (42.6%) had 361 non-serious adverse events because of a change in seizures. The most common were increased frequency of complex partial seizures (43 patients, 16.8%), new symptoms as part of a complex partial seizure (33 patients, 12.9%) and new symptoms as part of a simple partial sensory seizure (29 patients, 11.3%).

STATUS EPILEPTICUS

Status epilepticus, commonly referred to as status, is a term used to describe a seizure that lasts 30 minutes or longer. Eight (8) of the 256 patients (3.1%) were hospitalized because of status epilepticus. One additional patient had status epilepticus after the neurostimulator and leads were removed, but while the patient was still in the study; the status occurred while the patient was being evaluated for epilepsy surgery with surgically implanted electrodes and had antiepileptic medications reduced.

1 patient had a non-serious adverse event because of status epilepticus. This patient was treated with oral medication as an outpatient.

SEIZURE-RELATED INJURY

Twenty-three (23) of the 256 patients (9%) had a serious adverse event because of an injury that occurred during a seizure. Some patients had more than one type of injury:

- 7 patients had a laceration (cut).
- 5 patients fractured a bone.
- 4 patients had bleeding in the brain or under the skull.
- 3 patients were burned.
- 2 patients had a head injury.
- 2 patients developed an implant site infection after falling during a seizure.
- 1 patient had a joint injury.
- 1 patient had a contusion (bruise).

103 patients (40.2%) had 370 non-serious adverse events because of a seizure-related injury. The most common were contusions (bruises) (43 patients, 16.8%), lacerations (cuts) (38 patients, 14.8%), and head injury (25 patients, 9.8%).

WITHDRAWALS AND DISCONTINUATIONS

As of May 12, 2011, in the combined RNS® System studies, 43 of 256 (16.8%) patients stopped participating in the RNS® System studies. Seven (7) patients were explanted because of infection, 1 patient was explanted because of hemorrhage, 3 patients were lost to follow-up, 9 patients died and 23 patients withdrew by choice. As of October 24, 2012, 11 patients had died.

NEUROSTIMULATOR REPLACEMENTS

There were 324 neurostimulators that were removed or replaced; 265 were replaced due to expected battery depletion. The usual amount of time until the neurostimulator was replaced because of expected battery depletion was 2.2 years.

Three (3) neurostimulators were replaced due to infection or erosion (skin breakdown). Eleven (11) neurostimulators were replaced during a procedure for lead revision. Eleven (11) neurostimulators were replaced due to premature battery depletion (this is discussed in detail below). One neurostimulator was replaced after a procedure to stop an unrelated cerebrospinal fluid leak. One neurostimulator was replaced because it was thought to be damaged after the patient was hit in the head. During a replacement procedure, one neurostimulator was not working and was replaced by another neurostimulator before the operative site was closed. No reasons were provided for 3 additional neurostimulator replacements.

Eleven (11) of the 256 patients had their neurostimulators replaced because the battery did not last as long as expected. These were batteries made by a certain manufacturer who no longer supplies batteries for the RNS® Neurostimulator.

There were 28 neurostimulator removal procedures. Thirteen (13) neurostimulators were removed due to infection (11) or scalp erosion (skin breakdown) at the incision site (2); two (2) were re-implanted at a later date. Other reasons for neurostimulator removal included epilepsy surgery (7), insufficient efficacy (3), to pursue other treatments (2), ongoing complaints (1), cerebral hemorrhage (1) and no reason provided (1).

Serious adverse events which occurred after the neurostimulator was removed included: 1 patient had a replacement of the bone at the implant site; 1 patient had worsening of tonic-clonic seizures (this patient later had the neurostimulator re-implanted); 1 patient had status epilepticus after the neurostimulator and leads were removed during evaluation for epilepsy surgery (this patient was already discussed).

LEAD DAMAGE, REMOVALS AND REVISIONS

There were 11 procedures to replace or revise 14 damaged leads in 10 patients. During 9 of these procedures the damaged leads were replaced. During 2 of these procedures the damaged leads were disconnected and a previously implanted lead was connected to the neurostimulator.

There were 27 procedures to change the leads location for sensing and stimulation; 15 of these changes occurred during a routine neurostimulator replacement. Ten (10) patients had their leads revised when their neurostimulator was replaced. This was to: implant a new lead (4), connect a lead that was already implanted to the neurostimulator (4), replace a lead due to high impedance (1), and to replace leads after a procedure to stop an unrelated cerebrospinal fluid leak (1).

There were 24 procedures in which leads were removed or left behind at the same time that the neurostimulator was removed; 9 were due to infection, 7 were due to epilepsy surgery, 3 were due to insufficient efficacy, 2 were done to pursue other treatments, 1 was after a cerebral hemorrhage, 1 was as a result of ongoing complaints and 1 patient had no reason provided.

Benefits

The RNS® System has been shown to reduce the frequency of disabling seizures in adults with partial onset seizures that have not been controlled with antiepileptic medications.

In the comparative study, seizure frequency was measured for 3 months in both the Treatment Group (received stimulation) and the Control Group (did not receive stimulation). The Treatment Group had a reduction in seizures of 37.9% and the Control Group had a reduction in seizures of 17.3%.

Seizure frequency was also measured by determining the number of patients who achieved a 50% reduction in seizures. During the 3 month Comparison Period 29% of patients in the Treatment Group and 27% of patients in the Control Group achieved a 50% or more reduction from baseline. There was no difference in the number of days without seizures and no difference in seizure severity between the Treatment and Control Groups.

After 1 year, almost half of the patients (44%) had at least 50% fewer seizures. And at 2 years, over half of the patients (55%) had at least 50% fewer seizures. Doctors could change antiepileptic medications after the Comparison Period (when all patients were receiving stimulation) as they thought was best for their patient. More than half of the patients did not have any medication changes (54%), 7.6% had their antiepileptic medications decreased, 22% had their antiepileptic medications increased and 16% had their medications both increased and decreased. Therefore, it is possible that some of the seizure reduction in some patients could have been due to changes in antiepileptic medications.

Quality of life (QOLIE) as measured by a questionnaire often used in epilepsy treatments was assessed. A significant clinical improvement on the QOLIE assessment is defined as an improvement of 5 points or more. 36.6% of patients in the Treatment Group and 39.1% of the patients in the Control Group had a significant clinical improvement at the end of the 3 month Comparison Period. At 1 and 2 years post-implant, 38% and 44% of patients (respectively) experienced a significant clinical improvement.

Specifications and Characteristics

Specifications and Characteristics

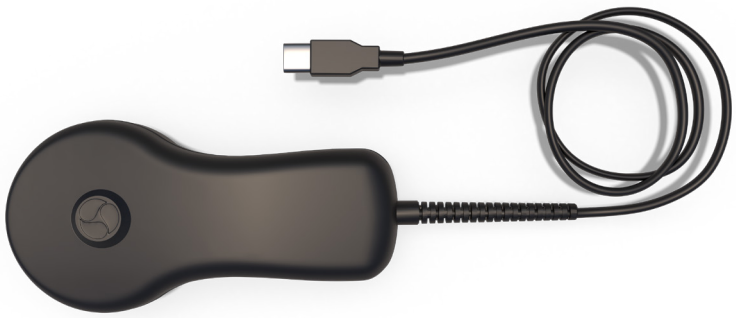
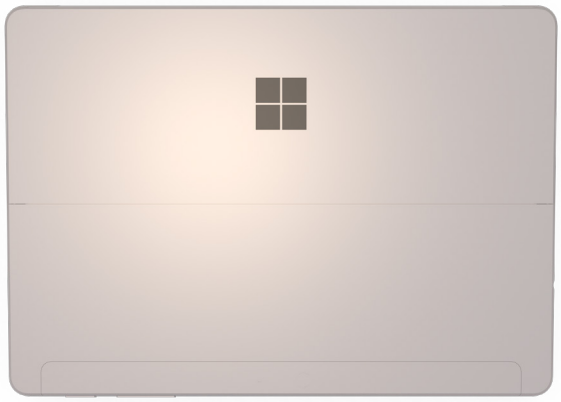


TABLE 5: WAND	
Dimensions (Length x Width x Depth)	7” x 3.5” x 1.3” (18 cm x 9 cm x 3 cm)
Weight	0.4 pounds (181 g)
Power Source	USB port of the remote monitor tablet
Operating Conditions	Temperature: 32 to 95 °F (0 to 35 °C) Humidity: 15 to 90%, non-condensing Atmospheric pressure: 700 to 1060 hPa
Material	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



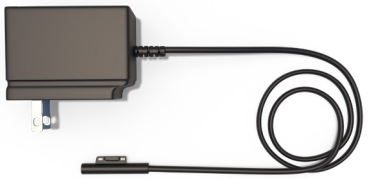


TABLE 6: REMOTE MONITOR TABLET COMPUTER*	
Dimensions (Height x Width x Depth)	245 mm × 175 mm × 8.3 mm (9.65” × 6.9” × 0.33”)
Weight	544 g (1.2 lbs)
Power Source	100 – 240 VAC, 50/60 Hz, 0.6A or internal rechargeable battery
USB Power Supply	5V, 500 mA
Operating Temperature	32 to 95 °F (0 to 35 °C)
Storage Temperature	-40 to 149 °F (-40 to 65 °C)

* These are typical, approximate values. Your tablet may be different.

TABLE 7: RNS® SYSTEM WIRELESS TELEMETRY	
Wireless Function	Transfer data between the neurostimulator and the remote monitor and wand
Wireless Technology Type	Short range, low power inductive coil to coil telemetry
Intended Use Environment	Clinical setting and home environment
Operating Range	0 – 3 cm
Frequency Band	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	37.25 nW or less

TABLE 8: REMOTE MONITOR WI-FI SPECIFICATIONS	
2.4 GHz Wi-Fi	
Frequency Band	2400-2483.5 MHz
Type	WLAN 2.4 GHz
Class	DTS
Modulation	BPSK / QPSK / 16QAM / 64QAM
Effective Radiated Power	24.24 dBm
5.0 GHz Wi-Fi	
Frequency Band	5150-5850 MHz
Type	WLAN 5.0 GHz
Class	U-NII-1 / U-NII-2A / U-NII-2C / U-NII-3
Modulation	BPSK / QPSK / 16QAM / 64QAM / 256QAM
Effective Radiated Power	24.24 dBm

If You Need Help

If You Need Help

IF YOU NEED HELP	
WHEN...	**THEN...**
You are having a medical emergency.	Call 911 Tell them you have the RNS System implanted.
• You are experiencing seizures with greater frequency or severity than before. • You need help with the use of the magnet. • You want to check if you can undergo a certain medical procedure or treatment while you have the RNS® System implanted. • You are unable to collect and send data to the PDMS database as your doctor has directed.	Contact the doctor who manages your RNS® System as soon as possible
• You need help with the set up or use of the remote monitor or wand. • You need to replace any part of the remote monitor, wand, or magnet. • You need more information about what to do when traveling through airport security and other surveillance systems.	Contact NeuroPace Customer Support at 866-726-3876

For additional patient resources, scan or go to:
www.neuropace.com/patients/current-rns-system-patients/

NEUROPACE CUSTOMER SUPPORT 866-726-3876 24-hr Support Line

THE RNS® SYSTEM

RNS® System Patient Manual

For the RNS® Neurostimulator Model RNS-300M and Model RNS-320 and the Remote Monitor Model 5106

For additional patient resources, go to:
www.neuropace.com/patients/current-rns-system-patients
or simply scan the QR code

You can also call us at 866-726-3876

NEUROPACE

NeuroPace, Inc.

455 N. Bernardo Ave.
Mountain View, CA 94043

NeuroPace Customer Support
866-726-3876

www.NeuroPace.com