



THE RNS® SYSTEM

Remote Monitor Manual

Model 5106





For additional patient resources, go to:
[www.neuropace.com/patients/
current-rns-system-patients](http://www.neuropace.com/patients/current-rns-system-patients)
or simply scan the QR code
You can also call us at 866-726-3876

Contents

2 FCC Information

2 Electromagnetic Emissions and Immunity and Wireless Technology

3 Symbols

4 Safety Information

Warnings...4

Cautions...7

Cybersecurity, Device Security, and Patient Information...10

12 About

Indications for Use...13

Purpose of Your Remote Monitor...13

14 Parts

Carrying Case...15

The Remote Monitor Software On Tablet Computer...15

Wand...15

Power Cord...15

16 Setup

Find a Good Place to Setup...17

Charge the Remote Monitor...17

Turn on the Remote Monitor...19

20 Basics

Tablet Touchscreen and Buttons...21

Home Screen...21

Connect to Wi-Fi...22

Wi-Fi Button on the Home Screen...24

Confirm Remote Monitor Setup...24

Turn Off The Remote Monitor...25

26 Get Data

30 Wand

Wand Signal Basics...31

Understanding Signal Level and Quality...32

Wand Too Far Away or Wand Disconnected...32

34 Update Center

Update Types...35

Update Options...35

Update Waiting...36

Update Process and Power Requirements...37

38 Travel

Airport Security...39

Traveling...39

40 Care and Maintenance

Care and Maintenance...41

Return / Disposal Of Tablet Computer And Wand...41

42 Troubleshooting

Remote Monitor Problems...43

Wand Problems...44

Data Collection Problems...45

Problems Uploading Data...46

58 If You Need Help

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

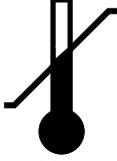
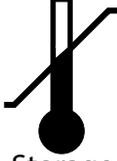
Medical Electrical Equipment needs special precautions regarding EMI and the following precautions should be taken before use.

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 48** 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		Type BF applied part
Rx Only	Prescription Only		Class II electrical protection
	Serial Number		
<u>5 V, 0.5 A</u>	Direct current (DC) 5 V (volts), 0.5 A (amperes)		
IP22	Ingress protection ratings: Level 2 for solid objects, which means testing confirms the device enclosure prevents ingress (entry) of items greater than 12.5 mm (~1/2 inch), such as fingers or similar objects; Level 2 for liquids, which means testing confirms vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.		

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

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 48](#) 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 48](#) 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 48](#) 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 to 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.

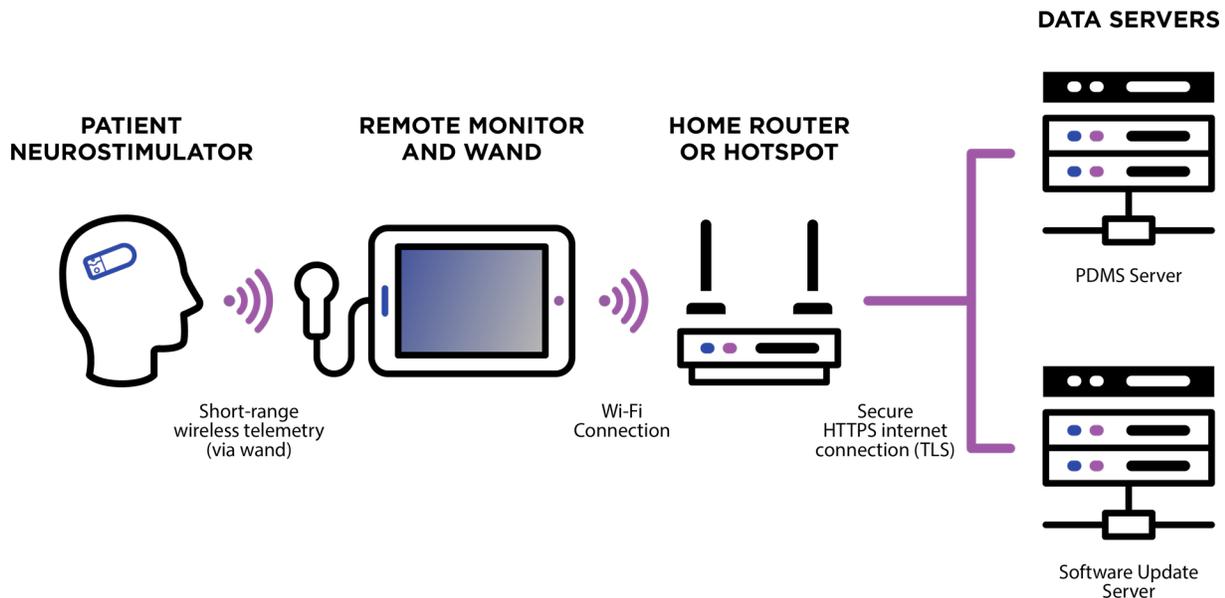
DO NOT move the remote monitor to another location without first disconnecting the parts and storing them in the carrying case. Disconnect the wand and all cords from the tablet. You may damage the parts if you do not disconnect them before moving them.

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 35***](#) 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

INDICATIONS FOR USE...13

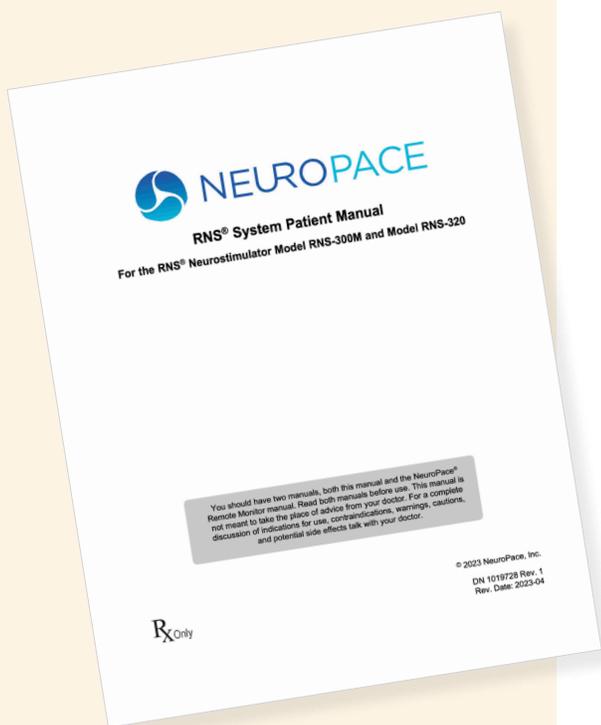
PURPOSE OF YOUR REMOTE MONITOR...13

About the RNS[®] System

INDICATIONS FOR USE

Refer to your RNS[®] System Patient Manual for the indications for use. For a complete discussion of indications for use, contraindications, warnings, cautions, and potential side effects, talk to your doctor.

The RNS[®] System Patient Manual has a cover that looks like this.



PURPOSE OF YOUR REMOTE MONITOR

The NeuroPace[®] Remote Monitor (5106) is designed for use with the RNS[®] Neurostimulator (models RNS-300M and RNS-320).

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

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

IMPORTANT INFORMATION

Please see your RNS[®] System patient manual for additional information regarding the RNS[®] System and treatment.

You must be willing to collect data from the neurostimulator 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 to the PDMS database automatically.

Parts

CARRYING CASE...15

THE REMOTE MONITOR SOFTWARE ON TABLET COMPUTER...15

WAND...15

POWER CORD...15



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 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 27](#).

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 17](#). 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 35](#).

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

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.

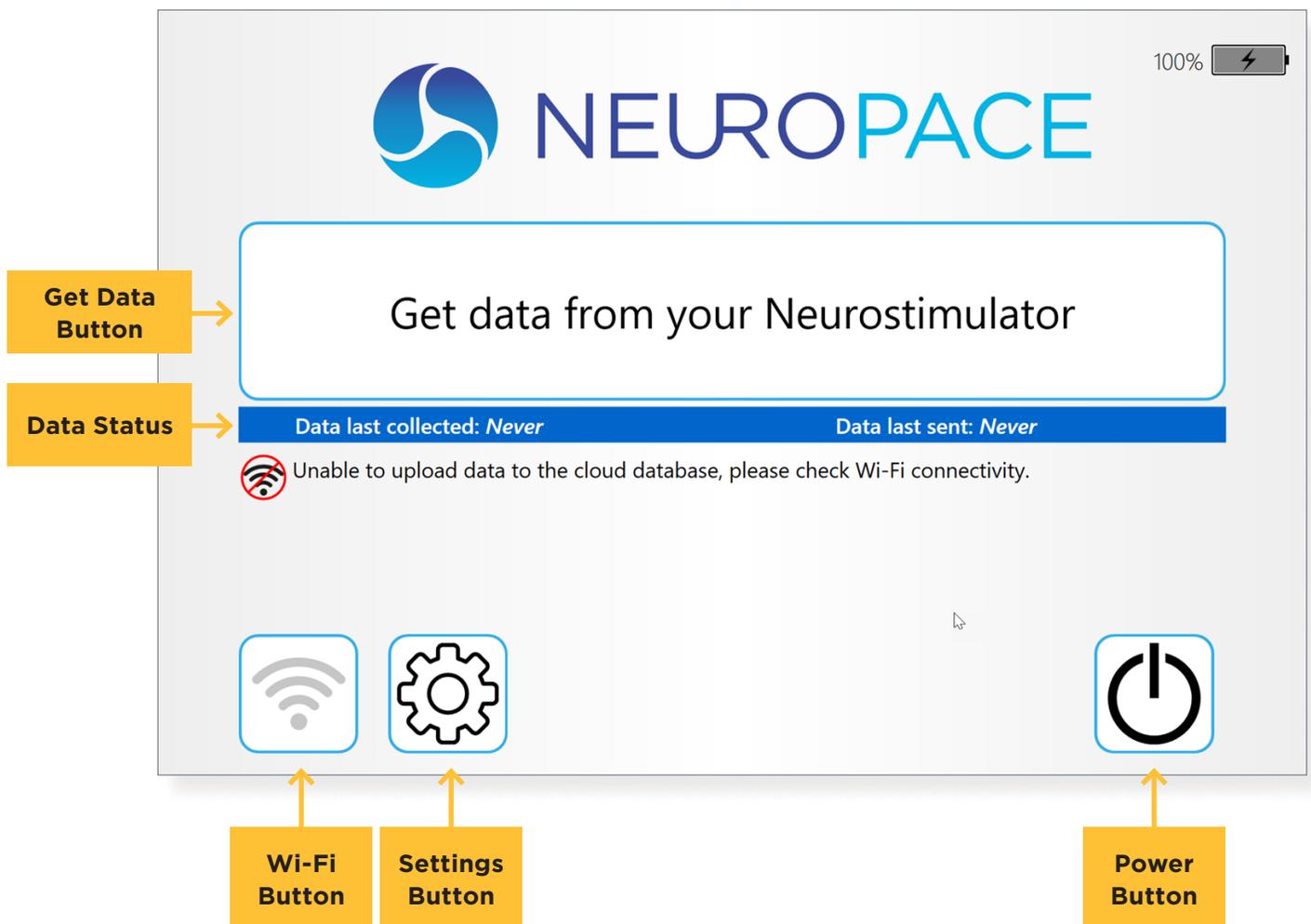
Note: Software screens that appear on the tablet and that are described below may not exactly match the screens that will appear on your tablet. This is due to differences in the type of tablet you may receive as part of the RNS® System.

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:



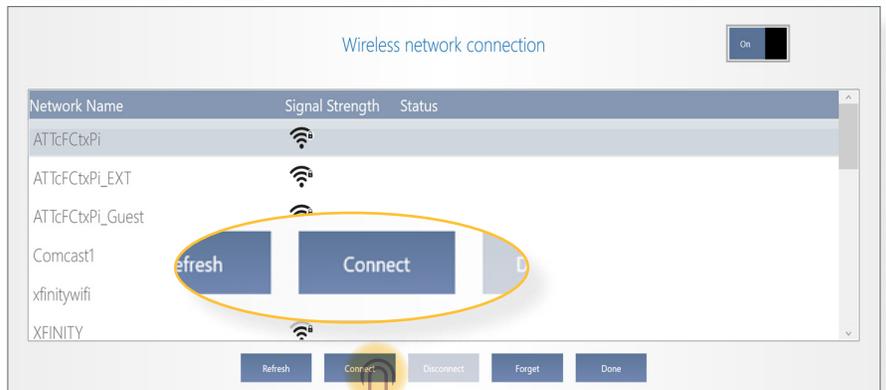
CONNECT TO WI-FI

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

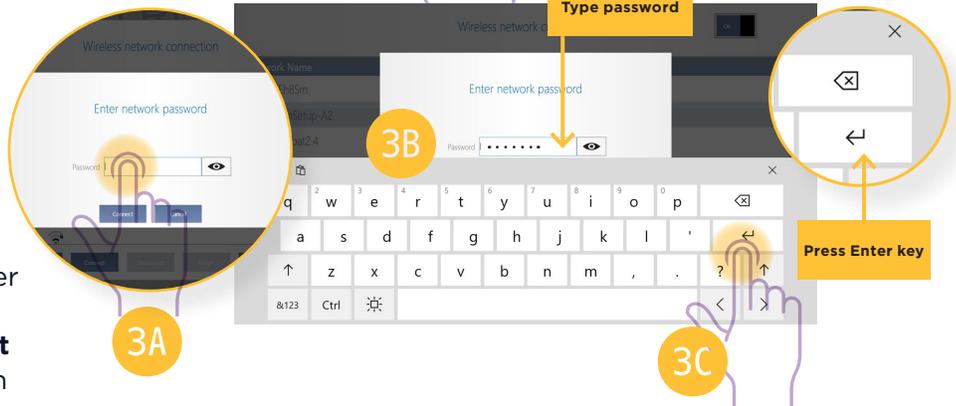
- 1 Touch the **Wi-Fi** button at lower left to view and select available wireless networks.



- 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.



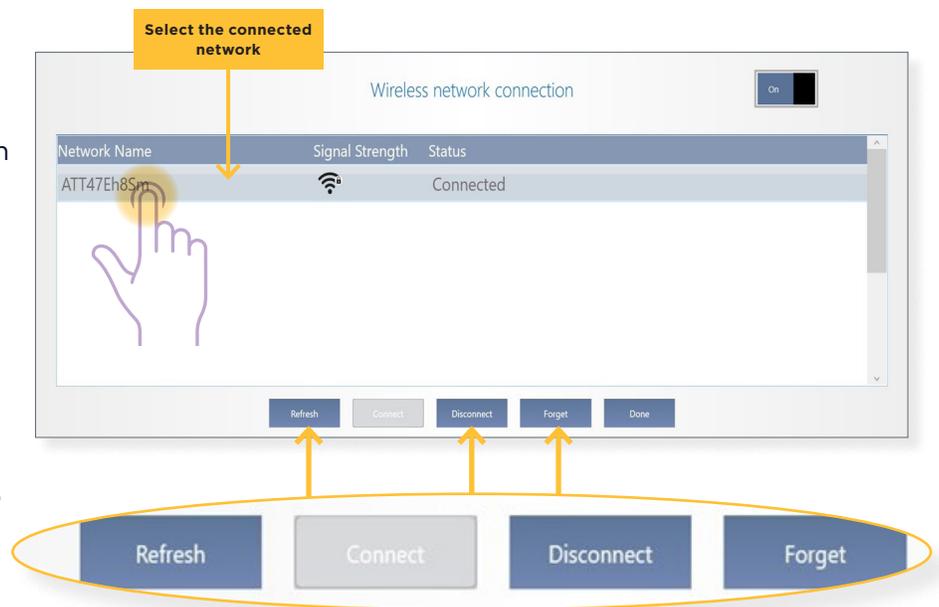
Note the following additional information and options about wireless network connections:

- 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.)

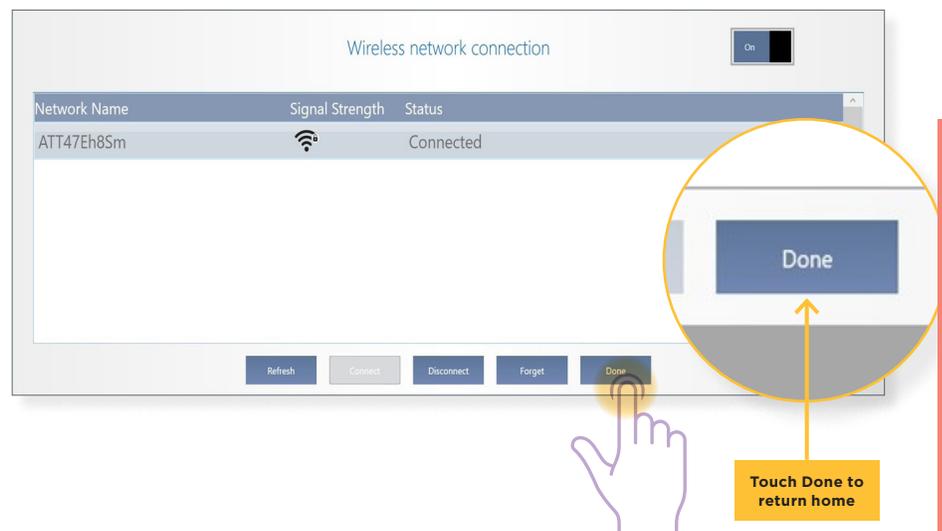


- Some public Wi-Fi networks require you to enter information into a web browser to connect to the Internet (for example, hotels or businesses). The remote monitor does not support a web browser for Internet communications, so you will not be able to enter that information to connect the remote monitor 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.

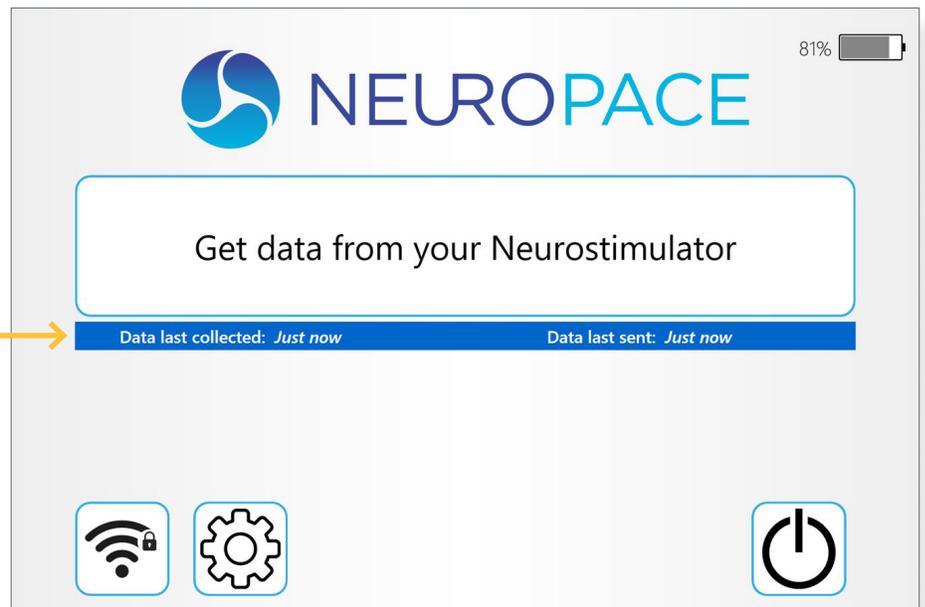


“OFF” with gray bars means Wi-Fi is off. Wi-Fi is on by default and should not be turned off. If it is off, touch to access the Wi-Fi On/Off button and turn on Wi-Fi.

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 27](#).

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 42](#) for information on how to solve the problem.

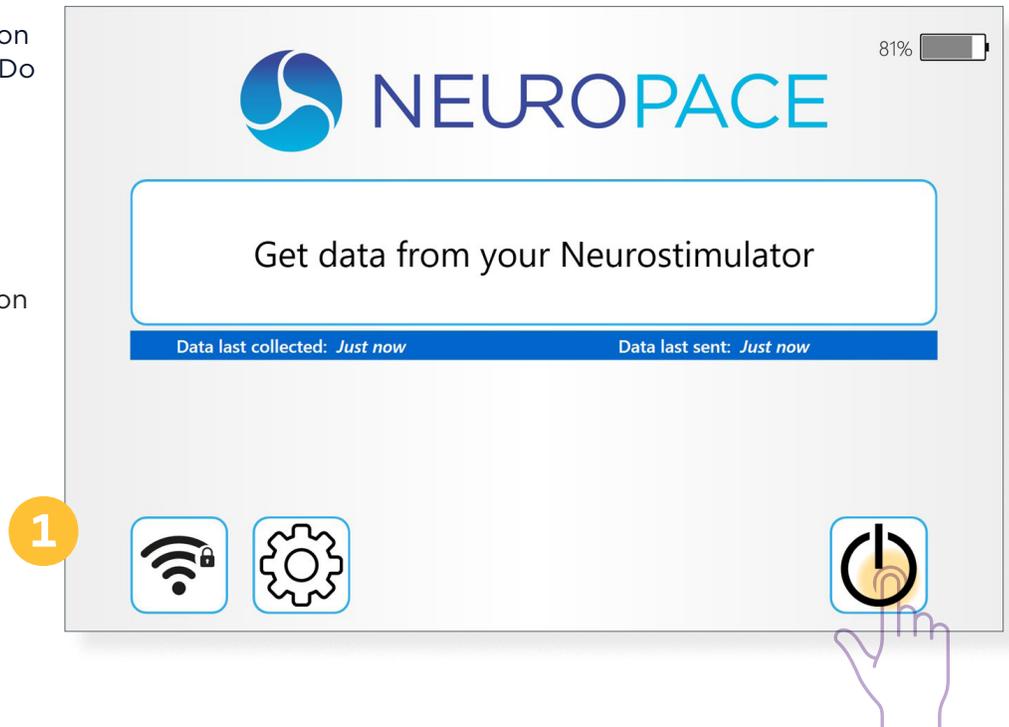


TURN OFF THE REMOTE MONITOR

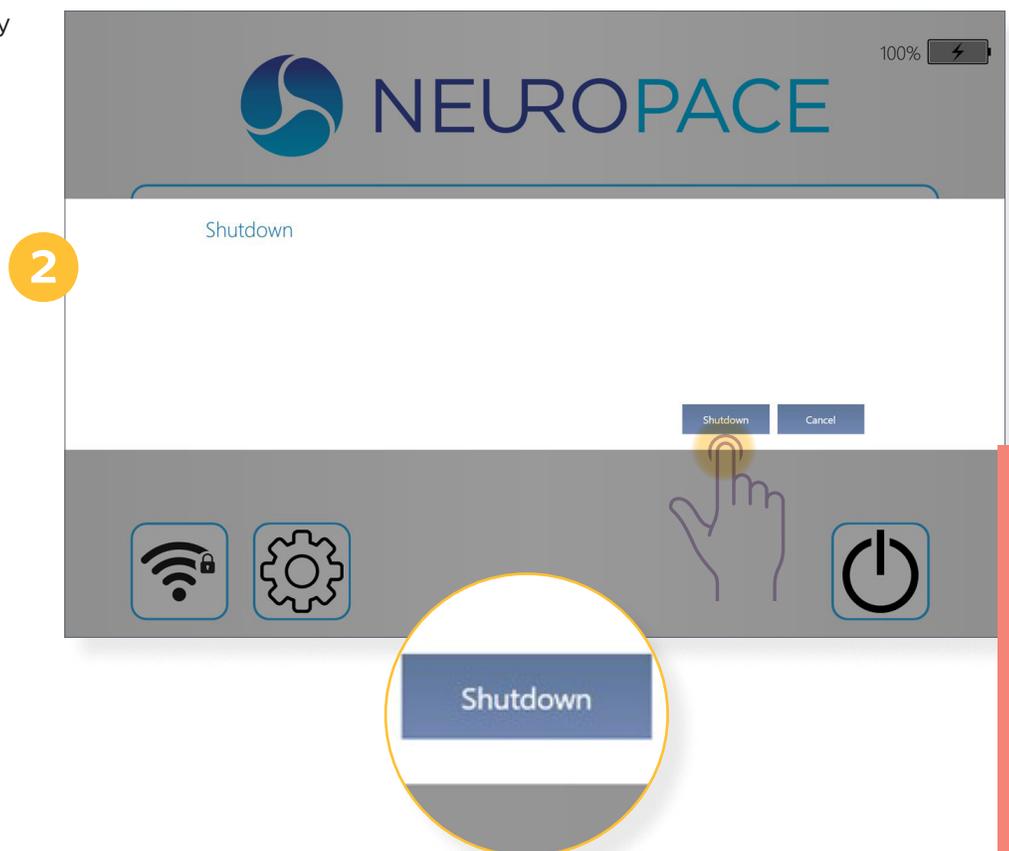
When you are finished using the remote monitor, be sure to turn it off. This will help conserve tablet battery power and electricity when not in use. The remote monitor tablet does not automatically go into “sleep” mode if you forget to turn it off.

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

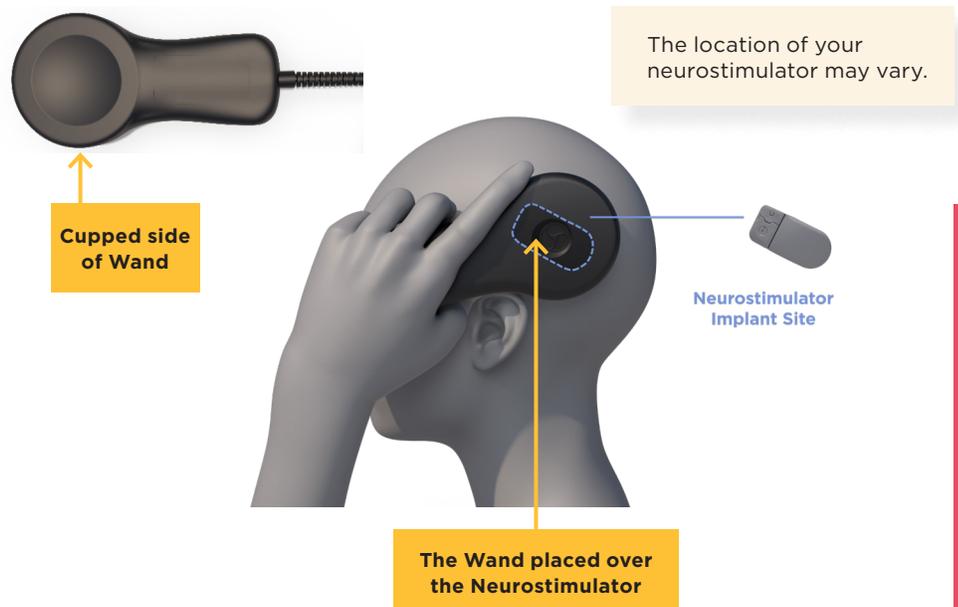
Get Data from Your Neurostimulator

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 32](#) and [Electromagnetic Emissions and Immunity on page 48](#) for more information.

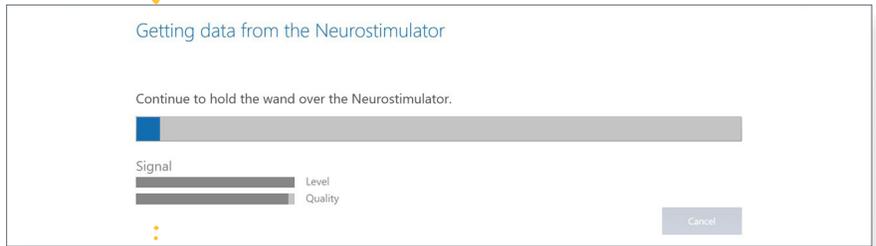
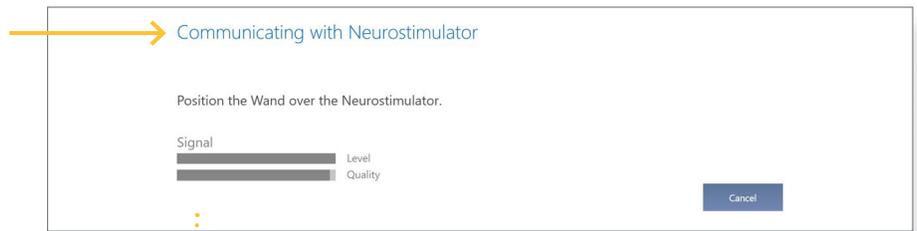
- 1 Turn on the remote monitor: Press the hardware power button. After checking for software updates, the Home screen appears.



- 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.



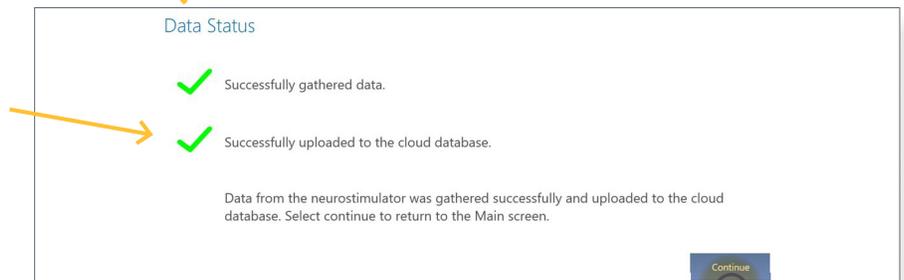
1 While holding the wand in place, touch **Get Data from your Neurostimulator** on the Home screen. The screen reports “Communicating with Neurostimulator” and then “Getting data from the Neurostimulator.” If it says anything else, read and follow the on-screen instructions to complete data gathering.



2 When the screen reports “Successfully gathered data,” you can put down the wand.

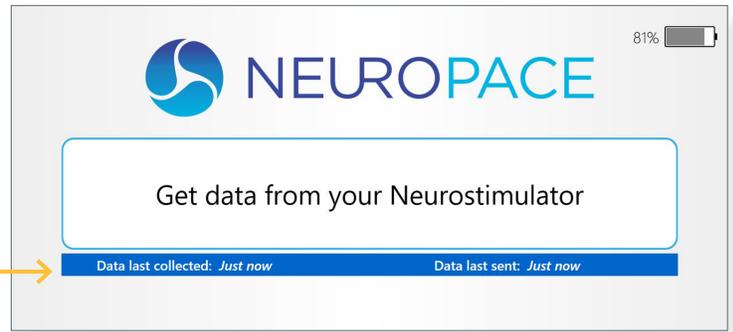
The remote monitor automatically starts transferring the data to the PDMS database, reports progress, and reports success when complete, as shown.

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

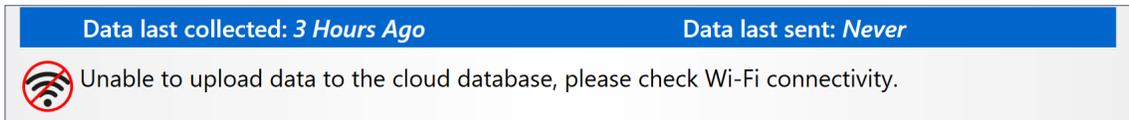


Normally it takes less than a minute to upload data, but it depends on the speed of your Wi-Fi connection. It is not necessary to monitor upload. If the device is not connected to Wi-Fi, the data will be uploaded automatically the next time it is connected. Nothing will be lost.

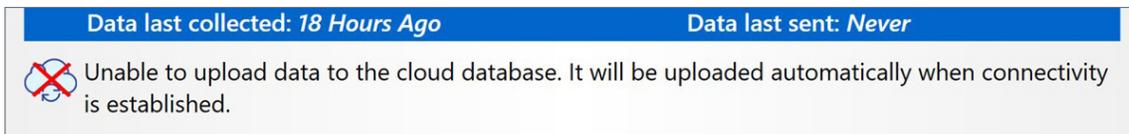
When you return to the Home screen, note that the blue bar in the middle of the screen displays the data status, which includes when the data was last collected (from the neurostimulator) and when the data was last sent (to the PDMS database). When you return, the text for both will say “Just now” if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

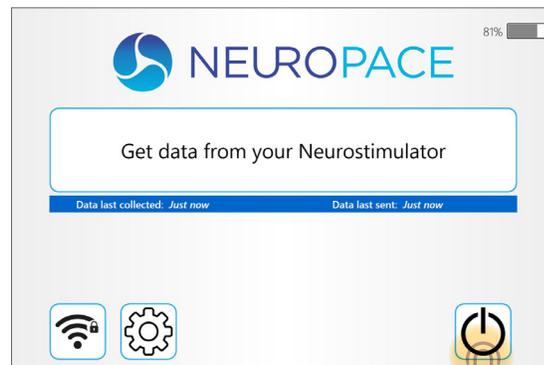


This message means that your remote monitor is not connected to Wi-Fi and you should touch the Wi Fi button at lower left to connect to an available network. Refer to [Connect to Wi-Fi on page 22](#). Once you connect to Wi-Fi, your data will be uploaded automatically.



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.



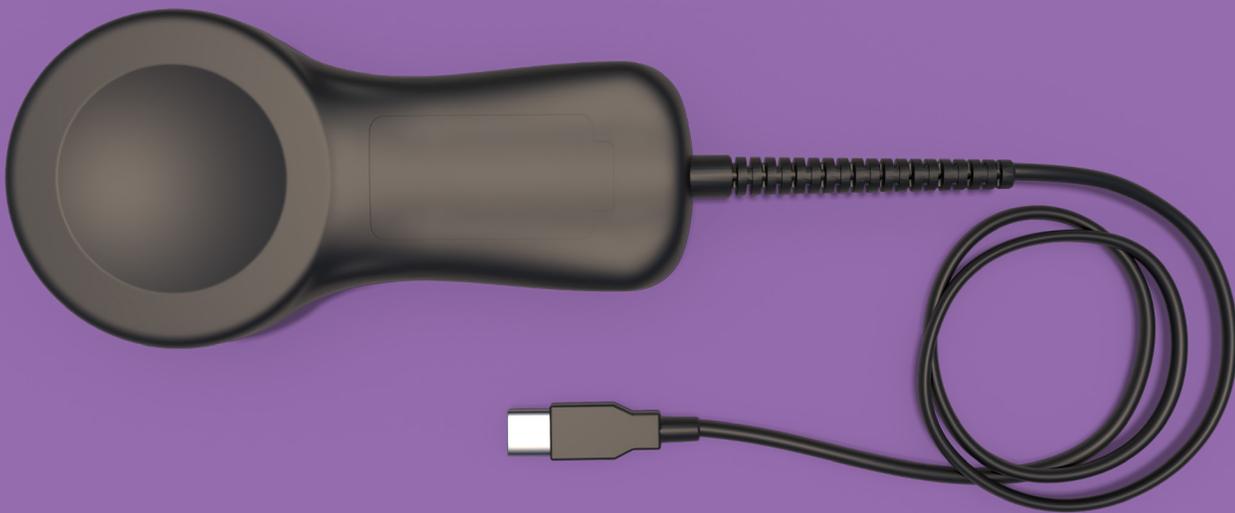
Use the Power button on screen to turn off the tablet. Do not use the hardware power button on top of the tablet except to turn it on.

Wand

WAND SIGNAL BASICS...31

UNDERSTANDING SIGNAL LEVEL AND QUALITY...32

WAND TOO FAR AWAY OR WAND DISCONNECTED...32



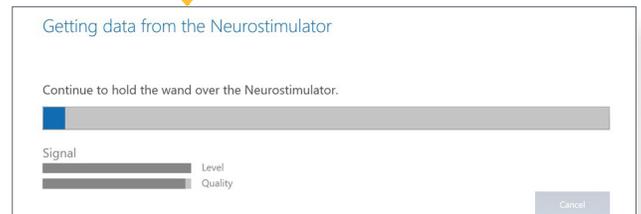
Wand Signal Basics

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 27](#).



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.

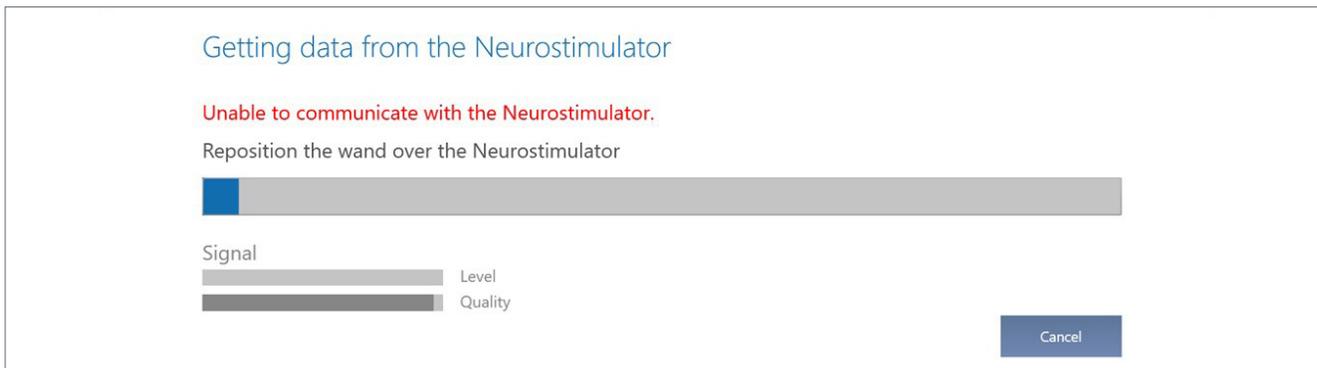
Move the wand over the neurostimulator until both bars are at least half full. Try to find the spot where signal strength is as close to the maximum level as possible.

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.

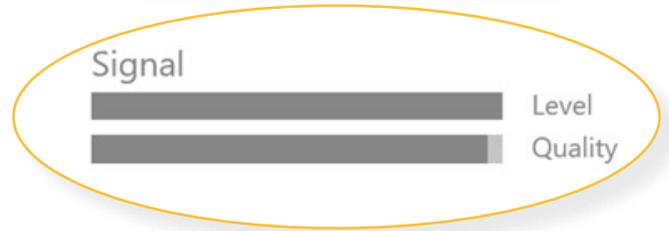
WAND TOO FAR AWAY OR WAND DISCONNECTED

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.”

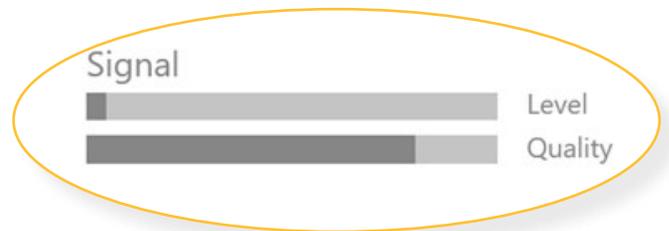


Move the wand closer to the neurostimulator until that message disappears, which means that data collection has resumed.

You can observe the level and quality of the wand signal

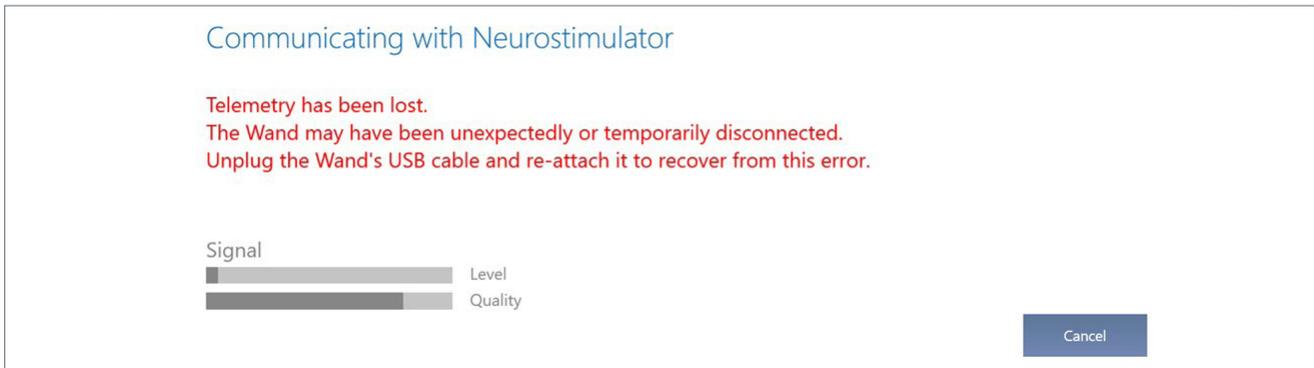


High Level, high Quality



Low Level, high Quality

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 45](#) for more information. If you still need assistance, contact NeuroPace Customer Support.

Update Center

UPDATE TYPES...35

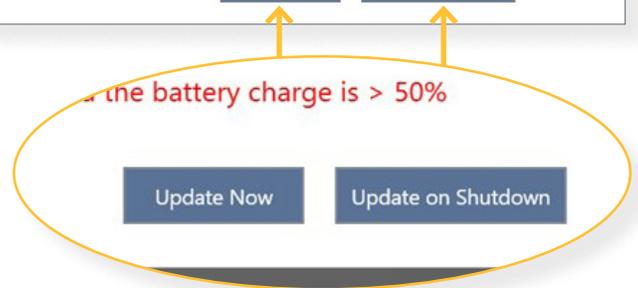
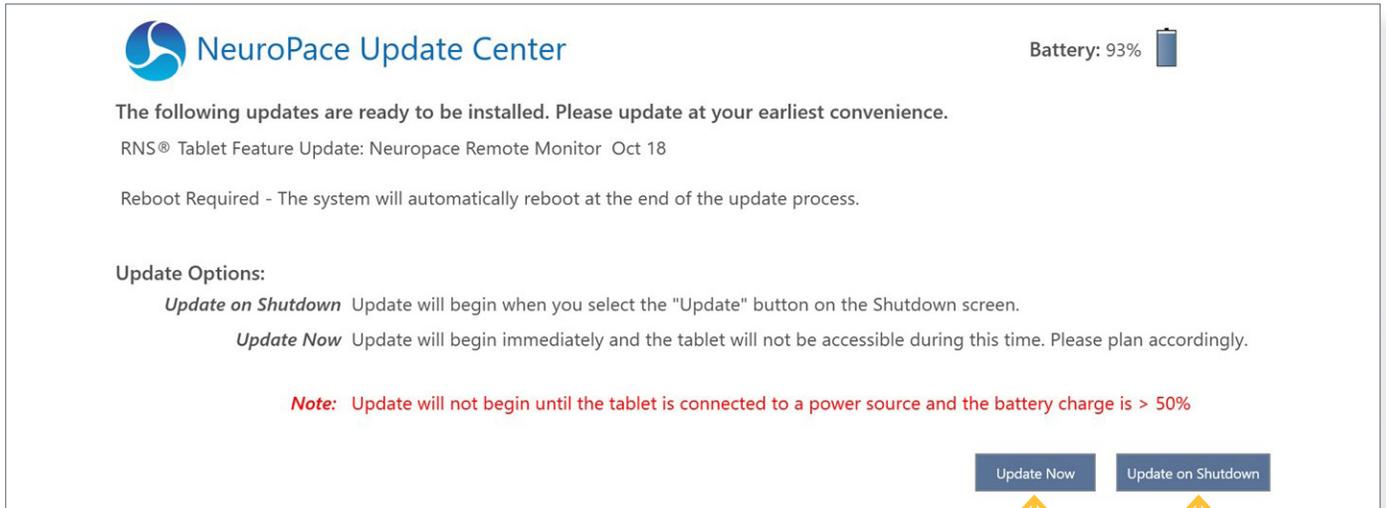
UPDATE OPTIONS...35

UPDATE WAITING...36

UPDATE PROCESS AND POWER REQUIREMENTS...37

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.

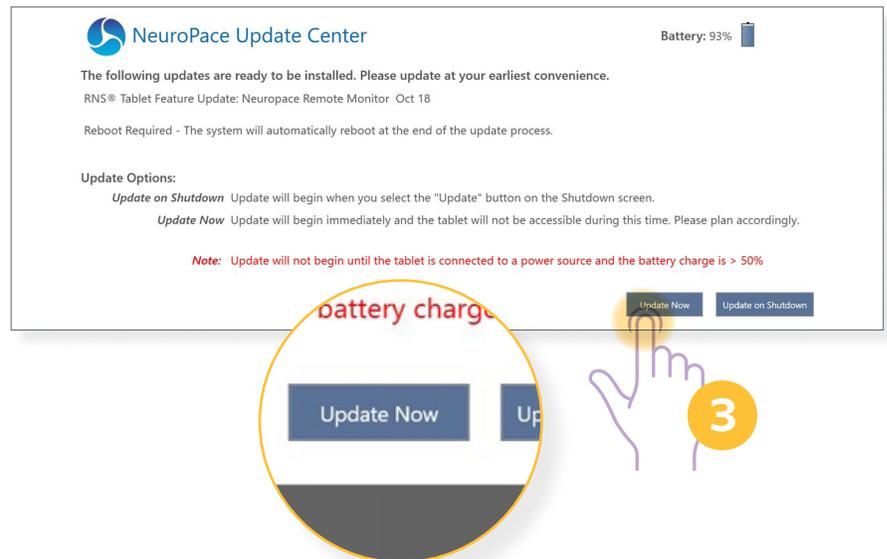
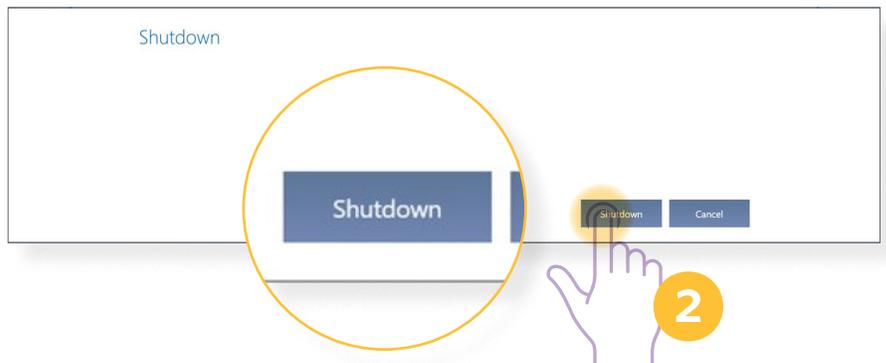
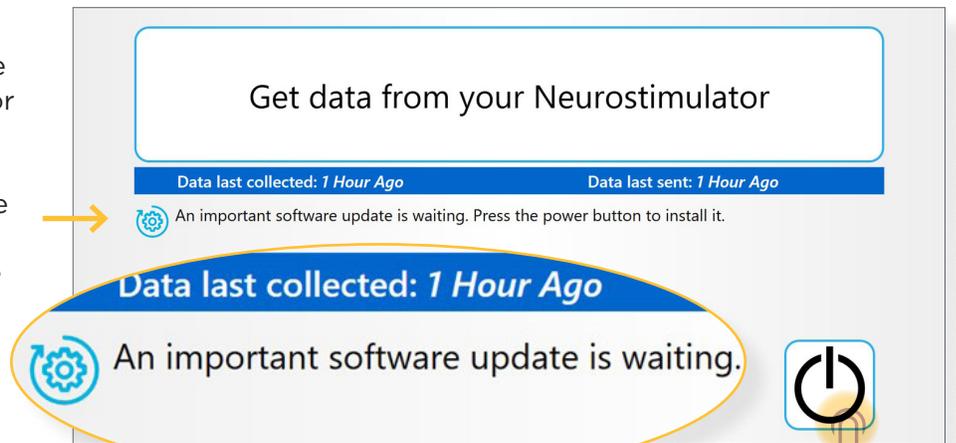
- 1 UPDATE NOW:** This option starts the update immediately and the tablet will not be available during this time.
- 2 UPDATE ON SHUTDOWN:** This option postpones the update until you shut down the tablet.

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:

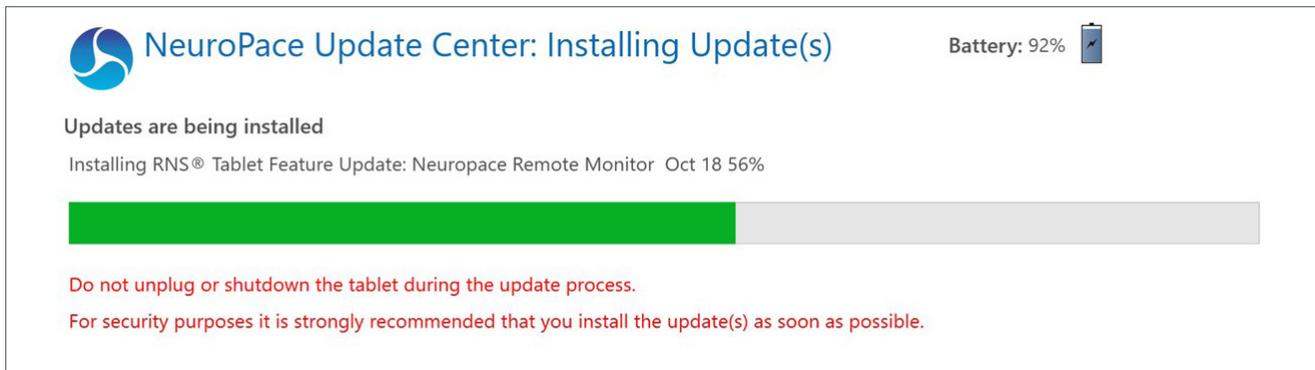
- 1 Press the power button at lower right on the Home screen.
- 2 Next touch the **Shutdown** button to turn off the remote monitor.
- 3 When you restart the tablet, the NeuroPace Update Center will appear: select **Update Now** to proceed with the update.

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.

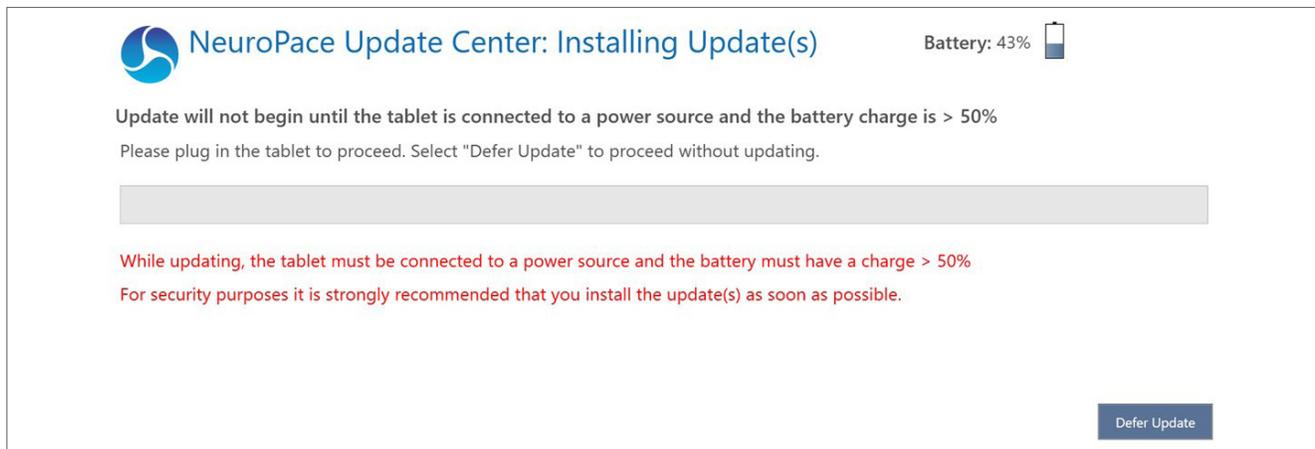


UPDATE PROCESS AND POWER REQUIREMENTS

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.



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

AIRPORT SECURITY...39

TRAVELING...39



Travel



AIRPORT SECURITY

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

TRAVELING

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

Care and Maintenance

CARE AND MAINTENANCE

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 43***](#) 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.

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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 27 and observe the signal level and quality bars. Refer to Understanding Signal Level and Quality on page 32. 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	<p>One of the following messages appears on the screen:</p> <ul style="list-style-type: none"> • “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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<p>The following message appears on the Home screen:</p> <div style="border: 1px solid #ccc; padding: 10px; background-color: #f9f9f9;"> <div style="background-color: #0070c0; color: white; padding: 5px; display: flex; justify-content: space-between;"> Data last collected: <i>3 Hours Ago</i> Data last sent: <i>Never</i> </div> <div style="padding: 10px;">  Unable to upload data to the cloud database, please check Wi-Fi connectivity. </div> </div>
Possible Causes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 22 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	<ul style="list-style-type: none"> • 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 22 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	<p>The following message appears on the Home screen:</p> <div style="border: 1px solid gray; padding: 5px; margin: 5px 0;"> <p style="text-align: center;">Data last collected: 18 Hours Ago Data last sent: Never</p> <p> Unable to upload data to the cloud database. It will be uploaded automatically when connectivity is established.</p> </div>
Possible Causes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.

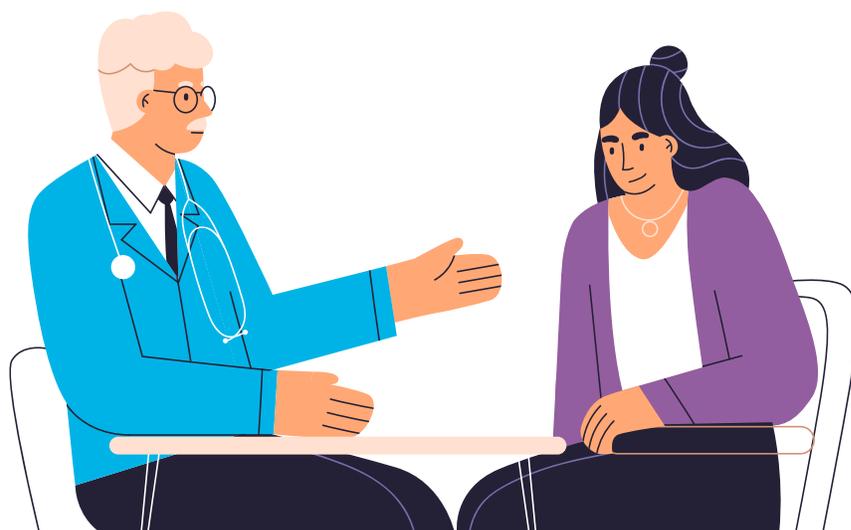
Electromagnetic Emissions and Immunity

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 6](#) 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 4](#) 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 4
Diagnostic ultrasound	●		
Diagnostic X-ray	●		
Electrolysis		●	See warning, page 4
Implanted cardiac devices		●	See warning, page 5
Lithotripsy		●	See warning, page 4
Medical procedures and dental work		●	See caution, page 7
Other active implanted medical devices		●	See caution, page 8
Radiation therapy		●	See warning, page 4
Removal and EMI considerations		●	See caution, page 8

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 6
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 7
Jackhammers		●	
Microwave ovens	●		
Personal computers, electric typewriters, copiers, and fax machines	●		
Portable and mobile RF communications equipment		●	See warning, page 6
Power lines and transmission towers		●	
Radiofrequency identification (RFID) sources		●	See warning, page 6
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) 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 ²	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 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}
Radiated immunity (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz ⁵	$d = 1.17\sqrt{P}$ (80 MHz to 800MHz) $d = 2.33\sqrt{P}$ (800 MHz to 2.7 GHz) Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Proximity field from RF Wireless Communications Equipment (IEC 61000-4-39)⁶	See table in footnote	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.
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	Interference may occur in the vicinity of equipment marked with the following symbol: 

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).

Footnote cont.

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 $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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.

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

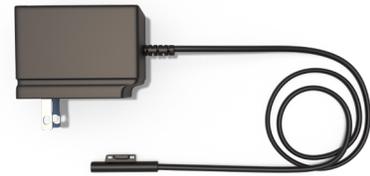
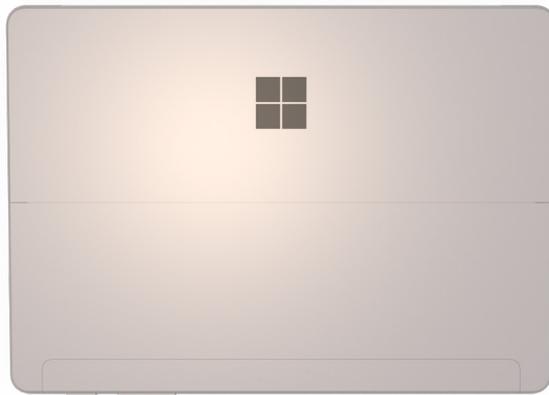


TABLE 6: REMOTE MONITOR TABLET COMPUTER*

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.	<p>Call 911</p> <p>Tell them you have the RNS System implanted.</p>
<ul style="list-style-type: none"> 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. 	<p>Contact the doctor who manages your RNS® System as soon as possible</p>
<ul style="list-style-type: none"> 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. 	<p>Contact NeuroPace Customer Support at 866-726-3876</p>



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

Remote Monitor Manual

Model 5106



For additional patient resources, go to:

[www.neuropace.com/patients/
current-rns-system-patients](http://www.neuropace.com/patients/current-rns-system-patients)

or simply scan the QR code

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