



**RNS<sup>®</sup> System Physician Manual**  
**For the RNS<sup>®</sup> Neurostimulator Model RNS-320**

**R<sub>X</sub>Only**

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DN 1019727 Rev. 3  
Rev. Date: 2024-11

## About this Manual

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This manual includes instructions for use for the RNS® System including:

- The RNS® Neurostimulator model RNS-320 with firmware version 7.101
- The NeuroPace® Cortical Strip Lead models CL-315-10, CL-325-10, and CL-335-10
- The NeuroPace® Depth Lead models DL-330-3.5, DL-330-10, DL-344-3.5, and DL-344-10
- The RNS® Tablet model 5000 with software version 1.9 and Wand model W-02

## FCC Information

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

- Neurostimulator 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.

# Symbols

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Explanation of symbols on product or package labeling

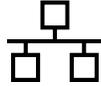
	Caution
	Do Not Resterilize
	MR Unsafe
	MR Conditional
	Prescription Only
	Non-Pyrogenic
	Single Use
	Sterilized Using Ethylene Oxide
	Temperature limits during use
	Temperature limits during storage or transport
	Manufacturer
	Serial number
	Type BF applied part
	Class II electrical protection

5 V, 0.5 A

Direct current (DC) 5 V (volts), 0.5 A (amperes)

IP22

Ingress protection ratings: Level 2 for solid objects, which means testing confirms the device enclosure prevents ingress (entry) of items greater than 12.5 mm (~1/2 inch), such as fingers or similar objects; Level 2 for liquids, which means testing confirms vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.



Ethernet Connection (Network Connection)

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



**WARNING:**

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

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

# Contents

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<b>Chapter 1: Introduction</b> .....	<b>1</b>
Contacting NeuroPace® .....	1
Typographic Conventions.....	1
<b>Chapter 2: RNS® System</b> .....	<b>2</b>
Indications for Use.....	2
Contraindications .....	2
<b>Chapter 3: Warnings and Cautions</b> .....	<b>3</b>
Warnings.....	3
Cautions.....	7
<b>Chapter 4: RNS® System Overview</b> .....	<b>12</b>
Implanted RNS® System.....	12
RNS® System Description.....	12
Theory of Operation.....	13
RNS® Neurostimulator (Model RNS-320).....	13
RNS® System Components and Accessories.....	14
NeuroPace® Cortical Strip Lead.....	14
NeuroPace® Depth Lead.....	15
Lead Components and Accessories.....	15
RNS® Tablet.....	15
Wand.....	16
NeuroPace® Patient Data Management System.....	16
Sterilization, Storage, and Handling.....	16
RNS® Neurostimulator Longevity.....	17
Medical Implant Identification Card.....	18
<b>Chapter 5: Clinical Use of the RNS® System</b> .....	<b>20</b>
Identify Candidates for the RNS® System Therapy.....	20
Localize the Seizure Focus and Plan Lead Location.....	20
Patient Training.....	21
Overview of Implantation and Programming of the RNS® System.....	21
<b>Chapter 6: Surgical Procedures</b> .....	<b>24</b>
Preimplant.....	24
Recommended Implant Procedure Flow Chart.....	27
Recommended NeuroPace® Depth Lead Implantation and Fixation.....	27
Recommended NeuroPace® Cortical Strip Lead Implantation and Fixation.....	30
Recommended RNS® Neurostimulator Implantation Procedure.....	30
Connecting the RNS® Neurostimulator to the Implanted Leads.....	32
Replacing or Explanting the RNS® System.....	36
<b>Chapter 7: Programming Instructions</b> .....	<b>43</b>
Electrode Impedance and Battery Voltage.....	43
Create the Recording Montage.....	44
Live ECoGs Screen.....	48
<b>Chapter 8: Magnet</b> .....	<b>50</b>
<b>Chapter 9: Troubleshooting</b> .....	<b>51</b>
Damaged Products.....	51
General Troubleshooting Activities.....	51
Abnormal Lead Impedance (greater than 3500 Ohms or less than 250 Ohms).....	51

Insufficient Charge.....	52
Noise, Artifacts, Poor Signal Displayed, or No Signal Displayed in Live ECoG.....	53
Poor or No Communication Between the RNS <sup>®</sup> Neurostimulator and the Programmer.....	54
Tablet Freezes or Does Not Turn Off.....	54
Tablet Does Not Turn On.....	54
Low Battery Measurement.....	55
Impedance Measurement Was Rejected / Test Request Was Rejected.....	55
RNS <sup>®</sup> Neurostimulator Reset (DC Leak Detected).....	55
<b>Chapter 10: Specifications and Characteristics.....</b>	<b>57</b>
RNS <sup>®</sup> System Specifications and Characteristics.....	57
Electromagnetic Emissions and Immunity.....	62
<b>Chapter 11: System Products, Components, Accessories, and Tools.....</b>	<b>68</b>
RNS <sup>®</sup> Neurostimulator Kits.....	68
NeuroPace <sup>®</sup> Cortical Strip Lead and NeuroPace <sup>®</sup> Depth Lead Kits.....	68
Surgical Accessory Kits.....	69
RNS <sup>®</sup> Tablet Kits.....	70
NeuroPace <sup>®</sup> Remote Monitor Kits.....	70
.....	71
<b>Glossary.....</b>	<b>72</b>



# Introduction

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## CONTACTING NEUROPACE®

All questions or concerns regarding the NeuroPace® RNS® System should be forwarded to:

NeuroPace, Inc.  
455 N. Bernardo Ave.  
Mountain View, CA 94043

Customer Support: 866-726-3876 (Toll Free in the United States)

Website: [www.NeuroPace.com](http://www.NeuroPace.com)

## TYPOGRAPHIC CONVENTIONS

This manual uses the following typographic conventions.

### **WARNING:** Warning Title

Warnings alert you to serious adverse events and potential safety hazards and situations that may cause injury.

### **Caution:** Caution Title

Cautions alert you to exercise special care.

**Note:** Notes provide additional information.

1. Numbered lists are used to identify a sequence of steps.

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This format is used to identify figure titles and descriptions.

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**BOLD SMALL CAPS** indicate on-screen text, like the names of screens, buttons and fields.

**Note:** Software version numbers found on screenshots in this manual are provided for illustrative purposes only and may not be the same as the version number you see on screen.

## INDICATIONS FOR USE

The RNS<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> System is contraindicated for:

- Patients 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.
- Patients who have medical devices implanted that deliver electrical energy to the brain.
- Patients who are unable, or do not have the necessary assistance, to properly operate the NeuroPace<sup>®</sup> Remote Monitor or magnet.

The following medical procedures are contraindicated for patients with an implanted RNS<sup>®</sup> System. Energy from these procedures can be sent through the implanted brain stimulation system and cause permanent brain damage which may cause severe injury, coma, or death. Brain damage can occur from any of the listed procedures even if the RNS<sup>®</sup> Neurostimulator is turned off or if the leads are not connected to the neurostimulator, and can occur even if the neurostimulator has been removed and any leads (or any part of a lead) or the cranial prosthesis remain.

- Diathermy procedures are contraindicated in patients implanted with an RNS<sup>®</sup> Neurostimulator and associated leads. (Diathermy is any treatment that uses high-frequency electromagnetic radiation, electric currents, or ultrasonic waves to produce heat in body tissues.) Patients 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) is contraindicated for patients with an implanted RNS<sup>®</sup> System.
- Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted RNS<sup>®</sup> System.

# Warnings and Cautions

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## WARNINGS

### Clinical Use

#### **WARNING:** Physician and Center Access to the RNS® System

The RNS® System should only be implanted by neurosurgeons with adequate experience in the implantation of subdural and stereotactic implantation of intraparenchymal electrodes and in the surgical treatment of intractable epilepsy. The RNS® System should only be used by neurologists or neurosurgeons with adequate experience in the management of intractable epilepsy and in the localization of epileptic foci, including the use of scalp and intracranial electrodes.

Neurologists and neurosurgeons using the RNS® System must have completed the NeuroPace® RNS® System training program. To qualify to manage patients with the RNS® System, physicians must demonstrate specific expertise related to epilepsy, video-EEG monitoring, interpretation of electrocorticograms (ECoGs), the pharmacology of antiepileptic medications and selection of patients for epilepsy surgery. Implantation of the RNS® System should be performed only by qualified neurosurgeons at centers capable of providing comprehensive epilepsy care, i.e. “Comprehensive Epilepsy Centers”. These centers should have the expertise to provide diagnostic services that include video-EEG monitoring with scalp and intracranial electrodes and neuroimaging, and are experts in the treatment of epilepsy with antiepileptic medications, epilepsy surgery, and devices.

#### **WARNING:** Management of patients with the RNS® System by physicians at centers that do not provide the services provided at comprehensive epilepsy centers

In some instances, post-implant programming may be conducted by neurologists meeting the experience and certification requirements for neurologists at Comprehensive Epilepsy Centers, but who are not practicing in such centers. This situation might occur if the patient is not able to travel to a Comprehensive Epilepsy Center for regular follow-up (e.g. because of distance from the Center or limited access to transportation). These neurologists will be qualified by NeuroPace to provide post-implant programming. After NeuroPace® RNS® System training is complete, the qualified programming neurologist may receive external NeuroPace products (programmer, remote monitor).

### Surgical

#### **WARNING:** Compatibility with Similar Implantable Products

The RNS® Neurostimulator, NeuroPace® Cortical Strip Lead, and NeuroPace® Depth Lead are not compatible with non-NeuroPace leads and/or pulse generators. Incompatible configurations may cause damage to the products and may result in unsafe current densities delivered to the patient.

#### **WARNING:** Cortical strip lead explantation

Explanting a chronically implanted cortical strip lead may cause tissue damage.

#### **WARNING:** Infection

Infection, including bacterial meningitis, may occur as a result of the RNS® System implant procedures and/or the RNS® System materials. Standard surgical infection prevention measures (antibiotics etc.) should be taken both pre- and post-implantation.

**WARNING:** Intracranial Hemorrhage

Intracranial hemorrhage may occur when implanting the RNS® System. Placing the leads, ferrule, and/or neurostimulator in an area where excess pressure may occur to the underlying blood vessels may cause intracranial hemorrhage. Patients with underlying risk factors for intracranial hemorrhage, such as patients with previous head trauma, anticoagulant use, or who experience head injury with seizures should be taken into specific consideration.

**WARNING:** Surgical Procedure Side Effects

Surgical procedure risks may include, but are not limited to, temporary pain at the implant site, CSF leakage and although rare, epidural hemorrhage, seroma, subdural or epidural hematoma, and paralysis.

**RNS® System and Therapy**

**WARNING:** Adverse Tissue Reaction

Allergic reaction to the implanted RNS® System materials and/or leads 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:** Skin Erosion

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

**WARNING:** Lead Migration

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

**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 malfunction, electrical short, open circuit, lead fracture, lead insulation failure, 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 neurostimulator 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:** Patient Data Collection

The patient must be willing to collect data daily from their neurostimulator and, if the patient has a laptop remote monitor, send the data to the PDMS database at least once a week.

**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:** 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 patient 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 by the patient.

Patients should exercise caution to avoid devices which generate a strong electric or magnetic field. Refer to [Electromagnetic Emissions and Immunity](#) on page 62 for more information.

**WARNING:** Radio Frequency Identification (RFID) Interference

Sources of RFID can result in signals that appear as ECoG activity to the neurostimulator. Signals that appear as ECoG activity could also result in delivering the programmed stimulation to the patient (per the device detection programming). The physician should be aware of possible sensing artifacts when assessing ECoG recordings. 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 62 for more information.

**WARNING:** Security and Electronic Tracking Systems

Security screening devices (such as theft detectors, security tag deactivators, and airport security screening devices) can result in signals that appear as ECoG activity to the neurostimulator. Signals that appear as ECoG activity could also result in delivering the programmed stimulation to the patient (per the device detection programming). Such devices may be found at retail stores, public libraries and airports. The physician should be aware of possible sensing artifacts when assessing the ECoG recordings. Patients should be instructed to walk through the center of such security screening units without stopping, when possible, and exit the area of the screening device as soon as possible.

Refer to [Electromagnetic Emissions and Immunity](#) on page 62 for more information.

**WARNING:** Interaction with Implanted Cardiac Devices

Possible effects of implanted device interaction with an implanted cardiac device (such as a pacemaker or defibrillator) include the following:

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation 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.

## Programmer

### **WARNING:** Potential Shock

Submerging any part of the programmer, or operating the programmer in or near a wet environment, may result in an electrical shock.

The programmer must be disconnected from the electrical outlet prior to cleaning to avoid the potential of electrical shock.

Electrical shock may occur if the programmer AC adapter and power cord are not properly connected to a grounded power source.

Do not attempt to modify or repair the wand or programmer. Contact NeuroPace Customer Support for assistance.

### **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<sup>®</sup> System and result in improper operation. Do not plug the wand into equipment other than the programmer because it could damage the wand. Do not use a USB cable extension from the programmer to the wand.

### **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<sup>®</sup> System, including cables. Otherwise, degradation of the performance of the RNS<sup>®</sup> System could result.

### **WARNING:** NeuroPace<sup>®</sup> Equipment Placement

Use of NeuroPace<sup>®</sup> 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<sup>®</sup> equipment and other equipment should be observed to verify that they are operating normally.

## Medical Environment

### **WARNING:** MRI Safety Information



**RNS<sup>®</sup> Neurostimulator model RNS-320:** An MRI scan may be safely performed on patients with the RNS<sup>®</sup> System (with RNS Neurostimulator model RNS-320) only under the specific conditions of safe use detailed in the MRI Guidelines for the RNS<sup>®</sup> System. Scanning under different conditions may result in device damage or malfunction and serious patient risks including permanent brain damage which may cause severe injury, coma, or death. All NeuroPace<sup>®</sup> manuals are available at [www.NeuroPace.com](http://www.NeuroPace.com) or by contacting NeuroPace, Inc.



**RNS<sup>®</sup> Neurostimulator model RNS-300M** of the RNS<sup>®</sup> System is MR Unsafe. Having an MRI scan with a model RNS-300M neurostimulator implanted may result in serious injury or possible death.

**RNS<sup>®</sup> System External Components:** All external components and accessories such as the Magnet, RNS<sup>®</sup> Tablet, NeuroPace<sup>®</sup> Programmer, NeuroPace<sup>®</sup> Remote Monitor, and Wand are MR Unsafe and can pose a projectile hazard in the MR environment, and therefore, must be kept out of the MRI scanner room.

**WARNING: Lithotripsy**

The effects of extracorporeal shock wave lithotripsy on the RNS<sup>®</sup> System have not been studied. Exposure to high-output ultrasonic frequencies may damage the RNS<sup>®</sup> System. This could result in loss of therapy, and additional surgery to remove or replace components of the RNS<sup>®</sup> System. Prior to any administration of lithotripsy, the administering physician should consult with the physician prescribing the RNS<sup>®</sup> System.

**WARNING: Radiation**

The effects of high radiation sources (such as cobalt 60 or gamma radiation used in cancer therapy) on the RNS<sup>®</sup> System have not been studied. Exposure to high levels of radiation may damage the RNS<sup>®</sup> System. This could result in loss of therapy, and additional surgery to remove or replace components of the RNS<sup>®</sup> System. Prior to any course of radiation therapy, the radiation oncologist should consult with the physician prescribing the RNS<sup>®</sup> System.

**WARNING: Electrolysis**

The effects of electrolysis on the RNS<sup>®</sup> System have not been studied. Electrolysis on the head or neck should be avoided.

**WARNING: Computerized Tomography (CT) Scans**

For CT procedures on a patient with an implanted RNS<sup>®</sup> Neurostimulator, the operator should:

- Ask the patient to have the neurostimulator temporarily shut off with a programmer while the scan is performed, if possible.
- Minimize x-ray exposure to the implanted electronic medical device by:
  - Using the lowest possible x-ray tube current consistent with obtaining the required image quality.
  - Making sure that the x-ray beam does not dwell over the device for more than a few seconds.

**Important:**

For CT procedures that require scanning over the medical device continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

After CT scanning, the operator should:

- Ask the patient to have the neurostimulator turned back on with a programmer if it had been turned off prior to scanning.
- Advise the patient to contact their healthcare provider as soon as possible if they have questions or suspect their device is not functioning properly after any medical procedure.

**CAUTIONS****Surgical****Caution: Connector Plug**

A vacant port in the connector cover must be filled with a connector plug (provided in the connector cover kit). There is an increased risk of neurostimulator failure if a connector cover port is vacant.

**Caution: Epidural Lead Placement**

Leads placed epidurally may cause pain during electrical stimulation.

**Caution: Lead Damage**

Bending, kinking, and stretching of the lead may cause lead damage. Handle the lead with care.

**Caution:** Sub-Galeal Lead Placement

Wrapping the lead(s) on/around the neurostimulator, or placing excess lead near the neurostimulator, may result in lead damage during subsequent surgical procedures.

**Caution:** Suture Sleeves

Suture sleeves are provided for use if sutures are used to stabilize the lead. Suturing directly on the lead may cause lead body damage and malfunction.

**RNS® System and Therapy**

**Caution:** Afterdischarge Activity

If evidence of afterdischarge activity resulting from stimulation is seen either on stored ECoGs or during test stimulation delivery, stimulation parameters should be adjusted to prevent such occurrence.

**Caution:** Battery Depletion

For continued operation, the neurostimulator needs to be surgically replaced when the battery is depleted.

**Caution:** Neurostimulator Longevity

High and frequent levels of stimulation reduce neurostimulator battery longevity.

**Caution:** Draining the Neurostimulator Battery

Testing the wand placement over the RNS® Neurostimulator for more than 10 minutes per day may drain the neurostimulator battery prematurely.

**Caution:** Frequency of Remote Monitoring

The patient should interrogate the RNS® Neurostimulator with the remote monitor and wand daily and, if the patient has a laptop remote monitor, synchronize the remote monitor with the PDMS at least once a week.

**Caution:** Explantation and EMI Considerations

If any system components (neurostimulator, leads, lead fragments, or cranial prosthesis) remain implanted in the patient after a partial system explant, the patient is still susceptible to possible adverse effects from strong sources of EMI. It is possible for the interference sources to couple enough energy into a neurostimulator system to damage brain tissue, resulting in serious patient injury or death. Patients who have system components implanted should exercise caution in avoidance of devices which generate a strong electric or magnetic field.

Refer to [Electromagnetic Emissions and Immunity](#) on page 62 for more information.

**Caution:** Lead replacement and abandoned leads

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

**Programmer**

**Caution:** Programmer Failure

As with any electronic device, the programmer may be damaged or malfunction if the programmer AC adapter and power cord are not properly connected to a grounded power source.

**Caution: Telemetry Artifact**

Telemetry may produce an electrographic artifact. If responsive therapy is enabled with sensitive detection settings, detection of the electrographic artifact may occur, resulting in therapy delivery. The physician should be aware of possible sensing artifacts when assessing the ECoG recordings.

**Medical Environment****Caution: Medical procedures**

Patients should always inform any healthcare personnel that they have an implanted RNS<sup>®</sup> System (and show their medical implant identification card) before any procedure is performed.

Advise the patient to contact their healthcare provider as soon as possible if they have questions or suspect their device is not functioning properly after any medical procedure.

**Caution: Electrosurgery**

The use of electrosurgery can affect the operation of neurostimulators. The RNS<sup>®</sup> System has been designed to prevent or minimize the effects of electrosurgery, however the energy levels used in electrosurgery can temporarily interfere with or cause permanent damage to device operation.

Electrosurgery applied near the RNS<sup>®</sup> Neurostimulator may cause it to temporarily stop sensing, delivering therapy, or may reset the neurostimulator. Under these conditions the neurostimulator may require interrogation and possible reprogramming.

Electrosurgery applied directly to the neurostimulator or leads may couple enough energy into a neurostimulator system to damage brain tissue.

If electrosurgery is necessary, the following recommendations may be effective in minimizing potential complications.

Before the procedure:

- If possible, temporarily disable stimulation using a programmer.

During the procedure:

- Use of bipolar electrosurgery is recommended and should be considered, whenever possible.
- Keep the electrosurgery tip more than 2 cm (approximately one inch) from the implanted device.
- The selected output power of the electrosurgery unit should be as low as possible for the relevant application and not used for greater than 10 seconds in any one burst.

After the procedure:

- If stimulation was temporarily disabled before the procedure, re-enable stimulation with the programmer and synchronize the programmer with the PDMS.
- Advise the patient to contact their healthcare provider as soon as possible if they have questions or suspect their device is not functioning properly after any medical procedure.

**Caution: Dental Therapy and Procedures**

Dental therapy and procedures that do not involve any of the procedures in the [Contraindications](#) on page 2 or [Warnings](#) on page 3 and following should be performed with caution. The dentist or dental technician should be informed that the patient is implanted with the RNS<sup>®</sup> System.

The following medical procedures may be performed without affecting the RNS<sup>®</sup> System:

- Diagnostic x-rays
- Diagnostic ultrasound

Advise the patient to contact their healthcare provider as soon as possible if they have questions or suspect their device is not functioning properly after any medical procedure.

**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. Exercise caution when other implanted devices are operating concurrently with the RNS® System. Possible effects include sensing problems and inappropriate device responses.

**Caution:** Incompatibility of Programmer with Other Medical Devices

The effects of using the programmer to interrogate other electronic, programmable devices such as pacemakers, defibrillators, cochlear implants, and other neurostimulators or CPAP machines are unknown. It could result in reprogramming of the other device and therefore, the physicians familiar with each device should check the programmed parameters of each device before the patient is discharged and after each programming session of either device.

**Caution:** Electronic Interference

Communications between the programmer and the implanted neurostimulator may be interrupted by emissions from nearby electronic devices. Examples of sources of EMI are lithotripsy, computer monitors, cellular telephones, motorized wheel chairs, x-ray equipment, and other monitoring equipment. Interruption of telemetry can result in incomplete communication. If EMI disrupts programming, move the programmer away from the likely source of EMI. Refer to *Poor or No Communication Between the RNS Neurostimulator and the Programmer* on page 54 for more information.

**Caution:** Placement of the Programmer Power Cord

Make sure nothing rests on the programmer power cord and that the cord is not located where it can be tripped over or stepped on.

**Caution:** Heating

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

**Home or Occupational**

**Caution:** Keep magnets at least 4 inches away from the implanted RNS® Neurostimulator

Magnets that are 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, should be kept at least 4 inches away from the neurostimulator. The neurostimulator may not deliver stimulation while these magnets are closer than 4 inches. Most headsets and earphones available in stores do not interfere with the RNS® System, but not all have been tested.

**Caution:** Magnet

Use care when handling the magnet as it may break if dropped and the broken pieces may have sharp edges.

**Caution:** Scuba Diving or Hyperbaric Chambers

Patients should 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:** Population for which safety and efficacy have not been established

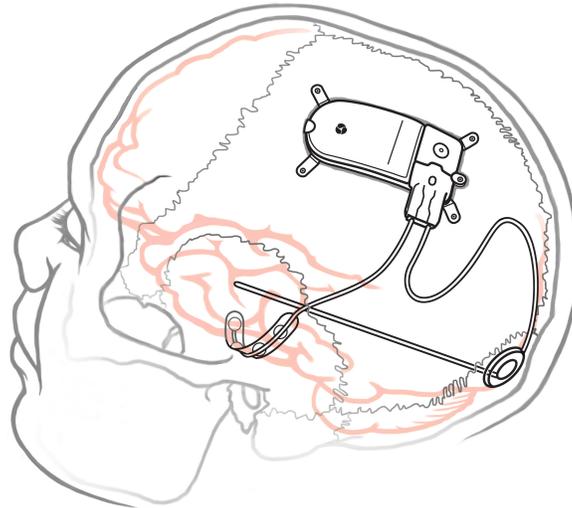
The safety and effectiveness of the RNS<sup>®</sup> System has not been established for:

- 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<sup>®</sup> System beyond 24 months is unknown.

## IMPLANTED RNS<sup>®</sup> SYSTEM



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**Figure 1:** The implanted RNS<sup>®</sup> System

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## RNS<sup>®</sup> SYSTEM DESCRIPTION

The RNS<sup>®</sup> System automatically delivers responsive electrical stimulation to reduce the frequency of partial onset seizures. Note that the RNS<sup>®</sup> System is not a seizure detection device. The RNS<sup>®</sup> System comprises sterile, implantable, and non-sterile external products.

### Implantable RNS<sup>®</sup> System Products

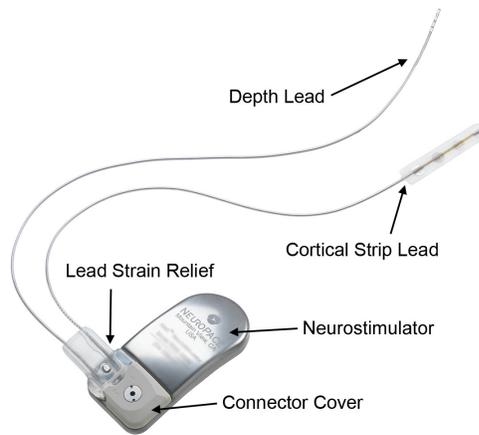
The sterile implantable products are the:

- RNS<sup>®</sup> Neurostimulator
- NeuroPace<sup>®</sup> Cortical Strip Lead and NeuroPace<sup>®</sup> Depth Lead
- Implantable components and accessories

### External RNS<sup>®</sup> System Products

The non-sterile external products are the:

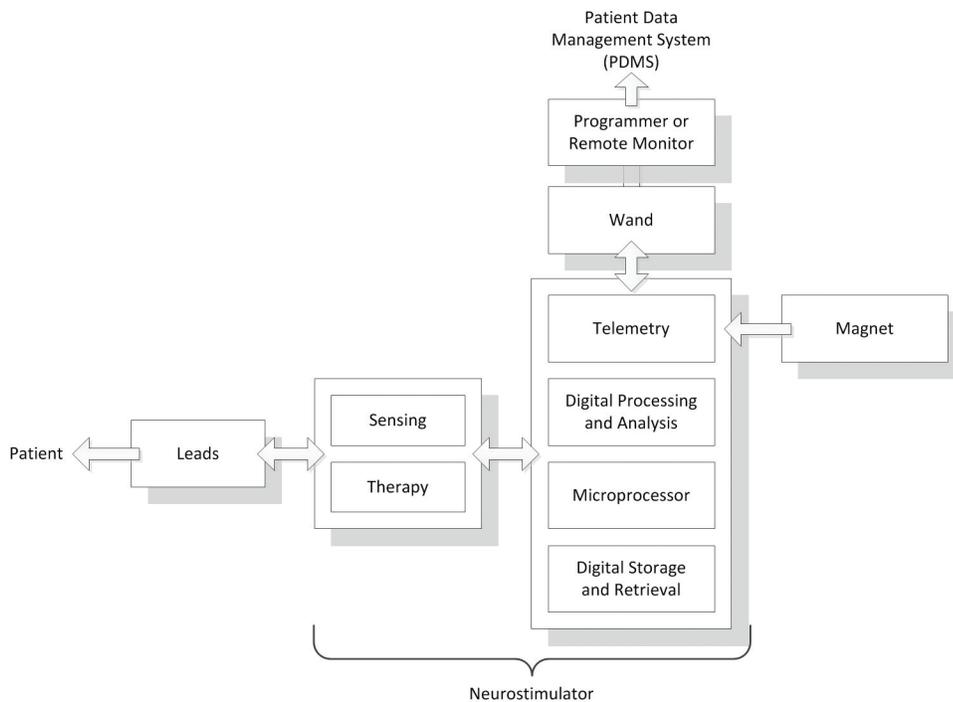
- RNS<sup>®</sup> Tablet and telemetry component (wand) used for communication with the RNS<sup>®</sup> Neurostimulator. For additional information, refer to the programming manual.
- NeuroPace<sup>®</sup> Patient Data Management System (PDMS) used for storage and access to historical neurostimulator and patient data. For additional information, refer to the programming manual.
- NeuroPace<sup>®</sup> Remote Monitor and wand used by the patient to gather information from the implanted RNS<sup>®</sup> Neurostimulator and upload it to the NeuroPace<sup>®</sup> Patient Data Management System. For additional information, refer to the remote monitor manual.
- The magnet can be used by a patient to mark a clinical seizure, and depending on how the physician programs the neurostimulator, to trigger electrocorticographic (ECoG) storage and withhold therapy.



**Figure 2:** RNS® Neurostimulator with two NeuroPace leads

## THEORY OF OPERATION

The RNS® Neurostimulator and implanted intracranial leads are designed to monitor electrical activity of the brain and deliver therapy in the form of electrical stimulation when appropriate. The neurostimulator is implanted in the patient and communicates with the programmer (and remote monitor).



**Figure 3:** The RNS® Neurostimulator senses and delivers therapy via the implanted leads. Communication with the neurostimulator is available using the programmer (and remote monitor).

## RNS® NEUROSTIMULATOR (MODEL RNS-320)

The RNS® Neurostimulator is a responsive electrical stimulation medical device. The neurostimulator senses and records electrocorticographic (ECoG) patterns from up to four amplifier channels. Upon detection of previously identified ECoG patterns, the neurostimulator delivers short trains of current pulses through the leads to interrupt those ECoG patterns. This is referred to as responsive electrical stimulation.

The RNS® Neurostimulator is a battery powered, microprocessor controlled medical device that is surgically implanted in the cranium and is covered by the scalp. The neurostimulator is connected to one or two leads that are surgically implanted within (depth lead) or on the surface (cortical strip lead) of the brain in the area of the epileptic seizure focus. Each lead contains four electrodes that can be assigned to one or two of four amplifier channels.

The RNS® Neurostimulator can be programmed to monitor and deliver responsive stimulation to one or two epileptic foci. Up to five individually configured sequential stimulations can be delivered when a specific ECoG pattern is detected. Each stimulation can contain two bursts that can be independently configured.

The RNS® Neurostimulator can store segments of electrocorticographic activity (electrocorticograms, ECoGs), neurostimulator status indicators, and records of events (including detections and therapies) detected by the neurostimulator. The neurostimulator can store up to a maximum of 53 minutes of ECoG activity segments.

A test stimulation function allows the user to test the current output of the neurostimulator and its effect on the patient.

**WARNING:** Compatibility with Similar Implantable Products

The RNS® Neurostimulator, NeuroPace® Cortical Strip Lead, and NeuroPace® Depth Lead are not compatible with non-NeuroPace leads and/or pulse generators. Incompatible configurations may cause damage to the products and may result in unsafe current densities delivered to the patient.

## **RNS® SYSTEM COMPONENTS AND ACCESSORIES**

### **Cranial Prosthesis**

The cranial prosthesis occupies a vacant ferrule if the neurostimulator has been explanted and not replaced.

### **Craniectomy Template**

The craniectomy template may be used as a pattern to mark and delineate the shape of the ferrule on the skull prior to making a craniectomy.

### **Connector Cover**

The connector cover secures the proximal lead contacts to the neurostimulator.

### **Connector Plug**

The connector plugs must be used to fill all vacant ports in the connector cover.

### **Ferrule and Ferrule Clamp**

The ferrule is installed in a craniectomy to secure and mechanically support the neurostimulator in the skull. The ferrule clamp is used to secure the neurostimulator to the ferrule.

### **Lead Strain Relief**

The lead strain relief supports the proximal end of the leads at their exit from the neurostimulator connector cover, protecting the leads from stress near the connector.

### **Magnet**

The magnet is a doughnut shaped magnet which, when swiped over the implanted neurostimulator, can be used to mark a clinical seizure. The magnet has additional uses which are dependent on neurostimulator programming.

### **Torque Driver**

The torque driver is used to tighten the screw that secures the connector cover to the neurostimulator and to tighten the ferrule clamp that secures the neurostimulator to the ferrule.

## **NEUROPACE® CORTICAL STRIP LEAD**

The NeuroPace® Cortical Strip Lead is intended for subdural implant to provide an interface through which electrical activity of the brain can be monitored and electrical stimulation can be delivered.

The NeuroPace® Cortical Strip Lead is available in the following lengths:

- 15 centimeters (Model CL-315-10)
- 25 centimeters (Model CL-325-10)
- 35 centimeters (Model CL-335-10)

There are four electrodes spaced 10 millimeters apart from each other. All four electrodes can be configured for sensing, detection, and stimulation.

**WARNING:** Compatibility with Similar Implantable Products

The RNS® Neurostimulator, NeuroPace® Cortical Strip Lead, and NeuroPace® Depth Lead are not compatible with non-NeuroPace leads and/or pulse generators. Incompatible configurations may cause damage to the products and may result in unsafe current densities delivered to the patient.

## NEUROPACE® DEPTH LEAD

The NeuroPace® Depth Lead is intended for implant into the brain to provide an interface through which electrical activity of the brain can be monitored and electrical stimulation can be delivered.

The NeuroPace® Depth Lead is available in the following configurations:

- 30 centimeter length, 10 millimeter electrode spacing (Model DL-330-10)
- 30 centimeter length, 3.5 millimeter electrode spacing (Model DL-330-3.5)
- 44 centimeter length, 10 millimeter electrode spacing (Model DL-344-10)
- 44 centimeter length, 3.5 millimeter electrode spacing (Model DL-344-3.5)

All four electrodes can be configured for sensing, detection, and stimulation.

**WARNING:** Compatibility with Similar Implantable Products

The RNS® Neurostimulator, NeuroPace® Cortical Strip Lead, and NeuroPace® Depth Lead are not compatible with non-NeuroPace leads and/or pulse generators. Incompatible configurations may cause damage to the products and may result in unsafe current densities delivered to the patient.

## LEAD COMPONENTS AND ACCESSORIES

### Tunneling Tool, Tunneling Tool Tip, Tunneling Straw

The tunneling tool components are used to tunnel an implanted lead from its cranial exit point, through a sub-galeal pathway, to the implanted neurostimulator location.

### Lead Cap

The lead cap protects the proximal end of a lead when it is not connected to the neurostimulator.

### Stop Gauge

The stop gauge is placed on a depth lead prior to implantation to indicate the appropriate depth of its insertion.

### Suture Sleeve

The suture sleeves protect the lead body when sutures are used to secure a lead.

## RNS® TABLET

The RNS® Tablet includes a tablet computer that runs proprietary NeuroPace software, and uses custom telemetry components to communicate with the RNS® Neurostimulator by holding the wand over it. The wand is applied to the patient (an applied part). Clinicians can use the tablet to program how the neurostimulator operates. Settings include, but are not limited to, the implanted system configuration, detection settings adapted to the patient's ECoG patterns, settings for ECoG record storage, and settings of the therapies. Clinicians can also use the tablet to review previously retrieved neurostimulator activity information, perform detection analysis, and communicate with the NeuroPace® Patient Data Management System (PDMS) via the Internet.

**Note:** The term “programmer” as used in this manual is a generic term that refers to the RNS<sup>®</sup> Tablet.

## **WAND**

The wand is applied to the patient (an applied part), placed over the implanted RNS<sup>®</sup> Neurostimulator to facilitate communication with the tablet (or remote monitor). It is connected to the tablet (or remote monitor) via a USB cable.

## **NEUROPACE<sup>®</sup> PATIENT DATA MANAGEMENT SYSTEM**

The Patient Data Management System (PDMS) maintains patient and product data obtained from the programmer and remote monitor. Authorized users may access the PDMS via the Internet using a personal computer. An electronic signature in the form of a user name and password are required for user authentication. For additional information on using the PDMS, refer to the programming manual.

## **STERILIZATION, STORAGE, AND HANDLING**

### **Handling Products**

The products of the RNS<sup>®</sup> System are to be handled with extreme care.

- Handle the lead with care.
- Bending, kinking, and stretching of the lead may cause lead damage.
- Do not reinsert stylet into the lead once it has been removed.
- Do not tighten sutures over the lead body.
- Only use the torque driver to secure the connector cover.

### **Resterilization of Implantable Products**

The RNS<sup>®</sup> Neurostimulator is provided sterile. **DO NOT RESTERILIZE.** Implantable RNS<sup>®</sup> System products are single use only. Do not resterilize or reimplant any explanted products of the RNS<sup>®</sup> System. Return the explanted neurostimulator and leads to NeuroPace.

### **“Use by” Date**

Do not implant or use any system component after the “Use by” date. Return all such product to NeuroPace.

### **Damaged Packaging**

Prior to product use, inspect the sterile packages for seal integrity. If the packaging appears to be wet, punctured, or damaged, the contents may no longer be sterile and the product should be returned to NeuroPace for replacement.

### **Product Storage**

Components should be stored in a clean and secure area with a room temperature of approximately 14 to 28 degrees Celsius.

### **Explant and Disposal**

Program all detection and therapy functions to DISABLED prior to explanting and shipping the RNS<sup>®</sup> Neurostimulator. Return the explanted neurostimulator and leads to NeuroPace. NeuroPace will provide shipping containers if requested.

DO NOT incinerate the neurostimulator; explosion can occur if the neurostimulator is exposed to incineration or cremation temperatures.

### **Return/Disposal of Programmer and Wand**

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

## Wand Maintenance, Cleaning and Sterilization

The wand is not user-serviceable and requires no maintenance. The wand can be cleaned by wiping with water. It can be placed in a sterile bag for use in the sterile field. DO NOT STERILIZE the wand.

## Electrostatic Discharge (ESD) / Static Electricity

The ports on the tablet may be sensitive to electrostatic discharge / static electricity. Handle the tablet ports carefully. If exposed to electrostatic discharge, the tablet may experience telemetry artifacts or errors, or may freeze. In the event of a tablet freeze, refer to [Tablet Freezes or Does Not Turn Off](#) on page 54.

## RNS® NEUROSTIMULATOR LONGEVITY

### RNS® Neurostimulator Battery

Neurostimulator longevity depends on the amount of stimulation delivered to the patient. Each time the neurostimulator delivers stimulation, a small amount of charge is drained from the battery. The battery information for each neurostimulator can be obtained through the PDMS. Battery measurements can be taken using a programmer.

### RNS® Neurostimulator Battery Life Estimation for Model RNS-320

The following battery information is theoretical. In actual use, the programmed stimulation parameters and other factors, such as lead impedance, may vary. Therefore, the following battery longevity estimates from beginning of battery life to end of service were calculated utilizing three patient use profiles: Low (5<sup>th</sup> Percentile), Medium (50<sup>th</sup> Percentile), and High (95<sup>th</sup> Percentile). It is important to note that the RNS® Neurostimulator is a responsive neurostimulator and does not have high, medium, and low operating settings.

**Table 1: Calculated Battery Longevity to End of Service (EOS) (Model RNS-320)**

Patient Use Profile	Battery Capacity (mAh)	Longevity Estimate* (years)
Low (5 <sup>th</sup> Percentile)	1114	12.4
Medium (50 <sup>th</sup> Percentile)	1114	10.8
High (95 <sup>th</sup> Percentile)	1114	6.0

\* Estimated battery longevity following 12 months of shelf storage. The estimates assume one MRI scan per year with 2 days in MRI Mode without affecting battery longevity. Each day in MRI Mode beyond this would reduce the longevity estimate by 0.35%. MRI Mode is necessary to protect the patient and the neurostimulator when having an MRI scan, but keeping the neurostimulator in MRI Mode uses more battery than when the device is in normal operating mode. While in MRI Mode, the neurostimulator is not detecting or delivering therapy to the patient. Therefore, it is strongly recommended that the neurostimulator remain in MRI Mode only for as long as necessary.

These patient use profiles were derived from data collected during the RNS® System Clinical Investigations in Epilepsy through May 12, 2011. The data (battery use in mAh/day) at the 5<sup>th</sup>, 50<sup>th</sup>, and 95<sup>th</sup> percentile levels were used to calculate the battery longevity estimates presented in [Table 1](#) on page 17.

These same data have been converted into the profiles in [Table 2](#) on page 18 to illustrate typical therapy parameters that would lead to the specified battery use. (Note that, e.g., half as many bursts per day with twice the burst duration would provide identical battery life.)

**Table 2: Patient Use Profiles**

Parameter	Unit	Low (5 <sup>th</sup> Percentile)	Medium (50 <sup>th</sup> Percentile)	High (95 <sup>th</sup> Percentile)
Current	mA	6	6	12
Frequency	Hz	200	200	200
Pulse Width	µsec	160	160	200
Burst Duration	msec	100	100	100
Bursts per day	-	100	570	1330

**Elective Replacement Indication (ERI)**

The tablet reports the neurostimulator battery voltage each time it is interrogated. The elective replacement indicator is displayed upon interrogation of the neurostimulator. The neurostimulator should be replaced promptly after the ERI notification. The ERI indicator is displayed approximately three months prior to the neurostimulator end of service (*Figure 4* on page 18).

**End of Service (EOS)**

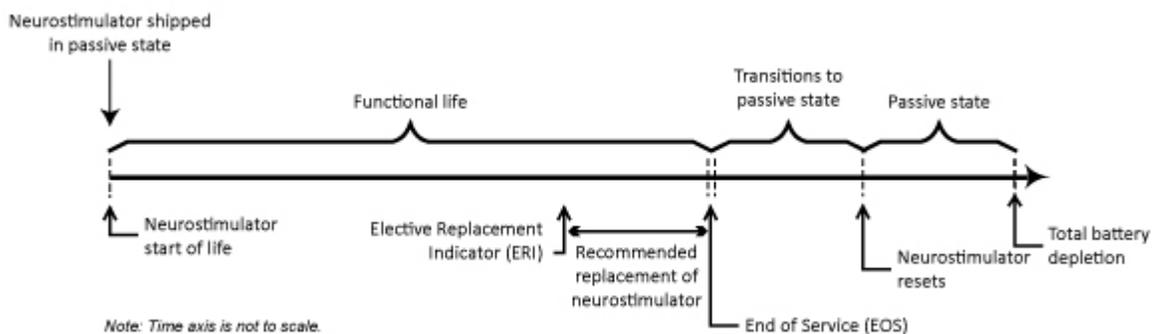
End of service is the point at which the RNS<sup>®</sup> Neurostimulator is no longer guaranteed to meet its specifications. The neurostimulator resets (and no longer detects or stimulates) within one week of EOS detection. The tablet can be used to indicate when the EOS battery level has been reached.

**RNS<sup>®</sup> Neurostimulator Reset**

When the neurostimulator resets, all of the neurostimulator functions are suspended except telemetry and battery measurement functions. The neurostimulator does not detect or deliver stimulation, measurements are disabled (except battery), and no records are stored. The neurostimulator resets if it detects an internal problem that it cannot correct, or if the neurostimulator battery voltage is at end of service. The tablet notifies the user of a reset upon neurostimulator interrogation.

**RNS<sup>®</sup> Neurostimulator Passive State**

The sterile, packaged neurostimulator is shipped in a passive state during which all neurostimulator functions are suspended except telemetry and battery measurement functions. The neurostimulator does not detect or deliver stimulation, measurements are disabled (except battery), and no records are stored. The first interrogation of a sterile, packaged neurostimulator by the tablet activates the neurostimulator.



**Figure 4:** The sequence of RNS<sup>®</sup> Neurostimulator battery life events

**MEDICAL IMPLANT IDENTIFICATION CARD**

NeuroPace packages a temporary medical implant identification card with the neurostimulator and leads. After implantation, NeuroPace associates the specific product information (for example, serial number) with

the patient information in the NeuroPace database. NeuroPace then mails a permanent medical implant identification card. Advise the patient to carry the medical implant identification card at all times.

# Clinical Use of the RNS® System

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## IDENTIFY CANDIDATES FOR THE RNS® SYSTEM THERAPY

Clinical trials have shown that the RNS® System is safe and effective in patients who are 18 years of age or older with disabling partial onset seizures from no more than two foci and have medically intractable epilepsy, defined by the International League Against Epilepsy (ILAE) as a failure to control seizures after 2 seizure medications that have been appropriately chosen and used.

Patients benefiting from the RNS® System have partial onset epilepsy with one or more of the following seizure types:

- Simple partial motor: seizures characterized by alteration in motor function without change in awareness
- Complex partial: seizure includes impairment in awareness
- Generalized tonic, clonic, or tonic-clonic seizures

The RNS® System is appropriate only in patients whose seizures begin in one or two foci that can be implanted with NeuroPace depth leads and/or cortical strip leads. Only 2 leads can be connected to the neurostimulator and therefore detection and stimulation can occur in no more than 2 locations.

The RNS® System is contraindicated in patients who have implanted medical devices that deliver electrical energy to the head. Patients who have medical or neurological conditions that place them at high risk for surgical complications are not good candidates for the RNS® System. For a complete list see [Contraindications](#) on page 2. An MRI scan may be safely performed on patients with the RNS® System (with RNS Neurostimulator model RNS-320) only under the specific conditions of safe use detailed in the MRI Guidelines for the RNS® System. An MRI scan with a RNS Neurostimulator model RNS-300M is unsafe. Please reference MRI Guidelines for the RNS® System which is available at [www.NeuroPace.com](http://www.NeuroPace.com) or by contacting NeuroPace, Inc.

## LOCALIZE THE SEIZURE FOCUS AND PLAN LEAD LOCATION

The RNS® System delivers responsive stimulation to one or two seizure foci. In order to accomplish this, a precise detection of the electrocorticographic activity of interest must be achieved to provide stimulation to the seizure focus. If electrocorticographic activity of interest is not detected as intended, and/or stimulation cannot be delivered to the focus, it is possible that the seizure focus will not be adequately treated. Therefore, it is essential that the seizure focus be sufficiently well localized to guide lead placement.

Localization of the seizure focus is accomplished using standard localization tests available at qualified Comprehensive Epilepsy Centers. This will always include inpatient video-EEG monitoring with scalp electrodes with or without supplemental electrodes such as sphenoidal electrodes, as well as MRI with appropriate magnet strength and sequences for the detection of mesial temporal sclerosis and other common epileptogenic lesions.

Non-invasive EEG and MRI imaging may be adequate to determine the number and location of seizure foci. However, some patients may require additional testing with video-EEG monitoring with intracranial electrodes to identify or refine the localization of the seizure focus. This may also include intraoperative or extraoperative stimulation with subdural electrodes for functional cortical mapping. Additional imaging studies may include Positron Emission Tomography (PET), ictal single photon emission computed tomography (SPECT), functional MRI (fMRI) or magnetoencephalography (MEG). Neuropsychological testing and intracarotid amytal (Wada) testing is included in many Comprehensive Epilepsy Centers' localization evaluation.

Patients with medically refractory partial epilepsy following resective surgery should have had appropriate studies following the surgery to adequately localize the seizure focus or foci prior to implantation of the RNS® System.

The leads to be implanted are selected based on the location of the seizure focus. Cortical strip leads are recommended for seizure onsets on the surface of the cortex, where the cortical strip leads may be placed over the focus. Depth leads are recommended for seizure onsets beneath the cortical surface, such as

within the mesial temporal lobe or within subcortical lesions such as dysplasias, where the depth lead may be placed within the seizure focus.

Several lead lengths are available (refer to [NeuroPace Cortical Strip Lead](#) on page 14 and [NeuroPace Depth Lead](#) on page 15). The lead model selected should be the appropriate length to reach from the seizure focus to the neurostimulator with as little excess lead as possible.

Up to four leads can be implanted (no more than two depth leads). For example, two depth leads and two cortical strip leads, or one depth lead and three cortical strip leads could be implanted. Only two leads can be connected to the neurostimulator at a given time. Unconnected leads should be capped. Leads connected to the neurostimulator can be changed at a subsequent procedure if desired.

## PATIENT TRAINING

- Prior to the implant surgery, train the patient and/or caregiver how to use the remote monitor and wand, as well as how to use the magnet according to the patient labeling.
- After implantation, provide the patient with the medical implant identification card.
- Instruct the patient and/or caregiver to interrogate the neurostimulator every day using the remote monitor and wand, and, if the patient has a laptop remote monitor, to synchronize the remote monitor with the PDMS at least once a week (preferably every day).

## OVERVIEW OF IMPLANTATION AND PROGRAMMING OF THE RNS<sup>®</sup> SYSTEM

### Implant the RNS<sup>®</sup> Neurostimulator and Leads

The RNS<sup>®</sup> Neurostimulator is cranially implanted. A ferrule is secured to a full thickness craniectomy and then the neurostimulator is placed within the ferrule. The recommended location of the neurostimulator is in the parietal skull but this can be modified based on the location of the leads and the curvature of the patient's skull. The neurostimulator may be implanted and secured in the ferrule before or after the leads are implanted. Refer to [Surgical Procedures](#) on page 24 for instructions on implanting the RNS<sup>®</sup> Neurostimulator.

Leads are placed using standard neurosurgical techniques. Depth leads may be implanted using standard stereotactic techniques through a burr hole in the skull, then secured by a burr hole cover such as the NeuroPace<sup>®</sup> Burr Hole Cover. Cortical strip leads are implanted through a craniectomy, in a manner similar to standard strip lead placements, then secured using suture sleeves. Leads are tunneled under the scalp to the craniectomy. Refer to [Surgical Procedures](#) on page 24 for instructions on implanting the NeuroPace<sup>®</sup> Depth Lead and NeuroPace<sup>®</sup> Cortical Strip Lead.

When the implantation procedure is complete and while still in the operating room, the tablet is used to test lead impedances and to capture live ECoGs to ensure that there is good lead-tissue contact. Refer to [Electrode Impedance and Battery Voltage](#) on page 43 for instructions on checking lead impedances and [Live ECoGs Screen](#) on page 48 for instructions on capturing live ECoGs.

### Recommended Initial Detection and ECoG Capture Settings

The neurostimulator is initially programmed in the operating room to detect electrocorticographic activity (ECoG) and to capture ECoG segments containing activity that can be used to configure detection settings specific to the patient.

A bipolar electrode montage is used for sensing. The sensing montage must be configured in a bipolar manner. The recommended initial montage is to sense between neighboring contacts. For example, channel 1 should be programmed to sense the difference between electrode 1 on lead 1 and electrode 2 on lead 1.

The recommended initial detection settings are the default settings in the tablet. These settings detect changes in frequency and power of the ECoG (line length detector with a 75% threshold).

The neurostimulator is programmed to store segments of the ECoG when specific events occur. The physician selects which types of events trigger ECoG capture – these are called ECoG triggers. There are three recommended ECoG triggers to be programmed at implant. The first is a magnet swipe by the

patient, which could indicate that a clinical seizure has occurred. The others are saturation (high amplitude ECoG) and long episode (sustained changes in the ECoG), both of which could indicate an electrographic seizure.

Instructions for setting up the initial detection and ECoG capture parameters are provided in the programming manual.

After implantation, the patient should be instructed to interrogate their neurostimulator daily using the remote monitor and, if the patient has a laptop remote monitor, to transfer that data to the PDMS at least weekly so that sufficient data are stored for the physician's review. The patient should be seen approximately 2 weeks after implant so that the physician can review the detections using the stored ECoGs.

### **Recommended Initial Responsive Therapy Settings**

Responsive stimulation therapy should be enabled once the physician has determined the electrographic activity of interest is being detected.

Recommended initial responsive therapy settings are a frequency of 200 Hz, pulse width of 160  $\mu$ sec and burst duration of 100 ms. Current amplitude should be initially programmed at 1.0 mA. In general, stimulation should be delivered to the leads and electrodes from which electrographic patterns of interest are observed. For example, if electrographic activity of interest is observed on all channels, then the stimulation pathway should be configured to stimulate across all electrodes. However, if electrographic activity of interest is observed on only 2 channels, then the stimulation pathway should be configured such that current is delivered through only those electrodes with electrographic activity of interest.

**Table 3: Recommended Initial Responsive Therapy Settings**

Frequency	200 Hz
Pulse Width	160 $\mu$ s
Burst Duration	100 ms
Current	1.0 mA and adjusted as necessary
Electrodes	Those from which patterns of interest are observed

Stimulation should be tested while the patient is in the physician's office by using the therapy testing function. This ensures that the patient tolerates the stimulation settings and that there are no undesired changes in the ECoG. If the patient cannot tolerate the stimulation settings or there are changes of concern in the ECoG, the current amplitude should be reduced.

See the programming manual for instructions on setting up the initial stimulation parameters.

### **Modify Detection and Responsive Therapy Settings**

Once the neurostimulator is programmed to provide responsive stimulation, the patient should be seen at approximately 3 month intervals to determine whether detection and/or responsive therapy settings should be modified. At each patient visit, the physician reviews ECoGs that are stored on the PDMS or tablet.

The physician decides whether the detection settings should be modified based on the ECoG review. Detection settings should promptly detect ECoG activity and not detect on baseline activity. In addition to the line length detector, the neurostimulator has bandpass and area detectors (described in the section titled Setting up Detection). If the physician wishes to change which ECoG patterns are detected, the detectors may be adjusted or a different detection tool may be selected. For example, if the physician wishes to detect smaller changes in the ECoG amplitude, the line length detector can be programmed to be more sensitive. If the physician wishes to detect specific ECoG frequencies, the bandpass detector could be used. Different detection settings can be simulated on the ECoG segments that have been stored on the PDMS or tablet. This allows the physician to see how the modified detection settings perform, before deciding to program these settings into the neurostimulator.

The physician may choose to modify stimulation to improve the patient's clinical response. Although modifications can be made to the stimulation frequency, burst duration or pulse width, it is recommended that initial modifications be to increase the current amplitude by 0.5 mA increments, with each stimulation setting tested using the therapy testing function to ensure that it is well tolerated by the patient and there are no undesired changes in the ECoG such as afterdischarges.

See the programming manual for instructions on modifying detection and responsive therapy settings.

# Surgical Procedures

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Implanting physicians should have adequate experience in the implantation of subdural and stereotactic implantation of intraparenchymal electrodes, in the surgical treatment of intractable epilepsy, have completed the RNS<sup>®</sup> System training program, and be thoroughly familiar with all product labeling.

## PREIMPLANT

### Patient and Family Information

The potential risks and benefits of implanting the RNS<sup>®</sup> System and responsive electrical stimulation therapy should be discussed with the patient, legal guardians, and family members before the implant procedure. The patient should be counseled that diathermy procedures, ElectroConvulsive Therapy (ECT), and Transcranial Magnetic Stimulation (TMS) are contraindicated, even if the neurostimulator is turned off or has been removed, or if any leads or any part of a lead remain. The patient should also be counseled on other medical procedures to avoid and on RNS<sup>®</sup> System care and environmental hazards. The RNS<sup>®</sup> System patient manual outlines this information and should be provided to and reviewed with the patient prior to the RNS<sup>®</sup> System implant.

### Presurgical Antibiotics

To reduce the risk of infection, it is recommended that antibiotics be administered prior to surgery.

### Product Preparation

1. Order and obtain the RNS<sup>®</sup> Neurostimulator and appropriate leads for the implant, as determined in the surgical planning for this procedure.
2. Before opening the RNS<sup>®</sup> Neurostimulator and leads packaging, verify model numbers, use-by dates, and product sterility.
3. It is recommended that additional products be available in case product sterility or function is compromised.

### Number of Leads

A maximum of four leads may be implanted, only two of which may be depth leads. Only two leads may be connected to the neurostimulator at any time; it is recommended that a unique identifier be attached to each lead.

### Tablet Preparation

The tablet should be in the operating room. It is used for the following activities:

- Assigning lead types and serial numbers to the corresponding neurostimulator ports.
- Programming the montage, detection, and ECoG capture.
- Confirming lead integrity by performing lead impedance measurements.
- Viewing live ECoGs to verify sufficient lead-tissue contact.
- Troubleshooting neurostimulator and lead issues.

### Preimplant RNS<sup>®</sup> Neurostimulator Interrogation

The sterile, packaged neurostimulator should be interrogated using the tablet prior to implantation to verify battery voltage.

To interrogate the sterile, packaged neurostimulator:

1. Turn on the tablet and log in.
2. Place the wand within approximately 1 inch of the neurostimulator, concave side of wand facing the neurostimulator.

The neurostimulator is visible from the bottom (clear side) of the neurostimulator sterile packaging tray.

3. Select the **INTERROGATE** button on the tablet's start screen.
4. Review **MEASURED BATTERY VOLTAGE** on the **NEUROSTIM INFO** screen.



The Early, Mid and Late life voltage ranges provide an estimate of remaining battery life. When battery voltage reaches 2.40 Volts or less, an Elective Replacement Indicator (ERI) notice is displayed.

If interrogation fails or the battery voltage is < 2.92 V, return the neurostimulator to NeuroPace, and continue the procedure with another sterile, packaged neurostimulator.

To manually measure battery voltage after interrogating:

1. Go to the **NEUROSTIM INFO** screen.
2. Select **MEASURE** in the **MEASURED BATTERY VOLTAGE** area.

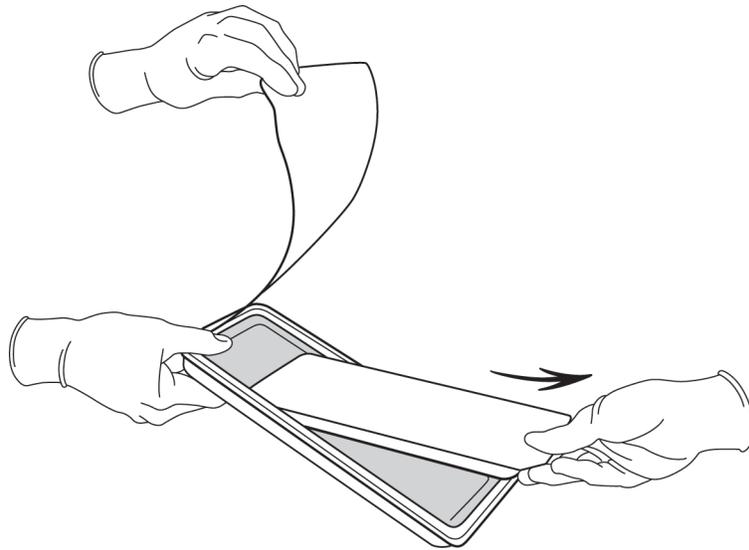


The Early, Mid and Late life voltage ranges provide an estimate of remaining battery life. When battery voltage reaches 2.40 Volts or less, an Elective Replacement Indicator (ERI) notice is displayed.

### **Open the Sterile Product Package**

Prior to opening the sterile packaging, inspect for any damage or breach in package seal integrity. If the packaging appears to be wet, punctured, or damaged the contents may no longer be sterile. Products with damaged packaging should be returned to NeuroPace for replacement.

Packages containing sterile products should be opened into a sterile surgical field. Products should not leave the sterile surgical field once the package is opened.



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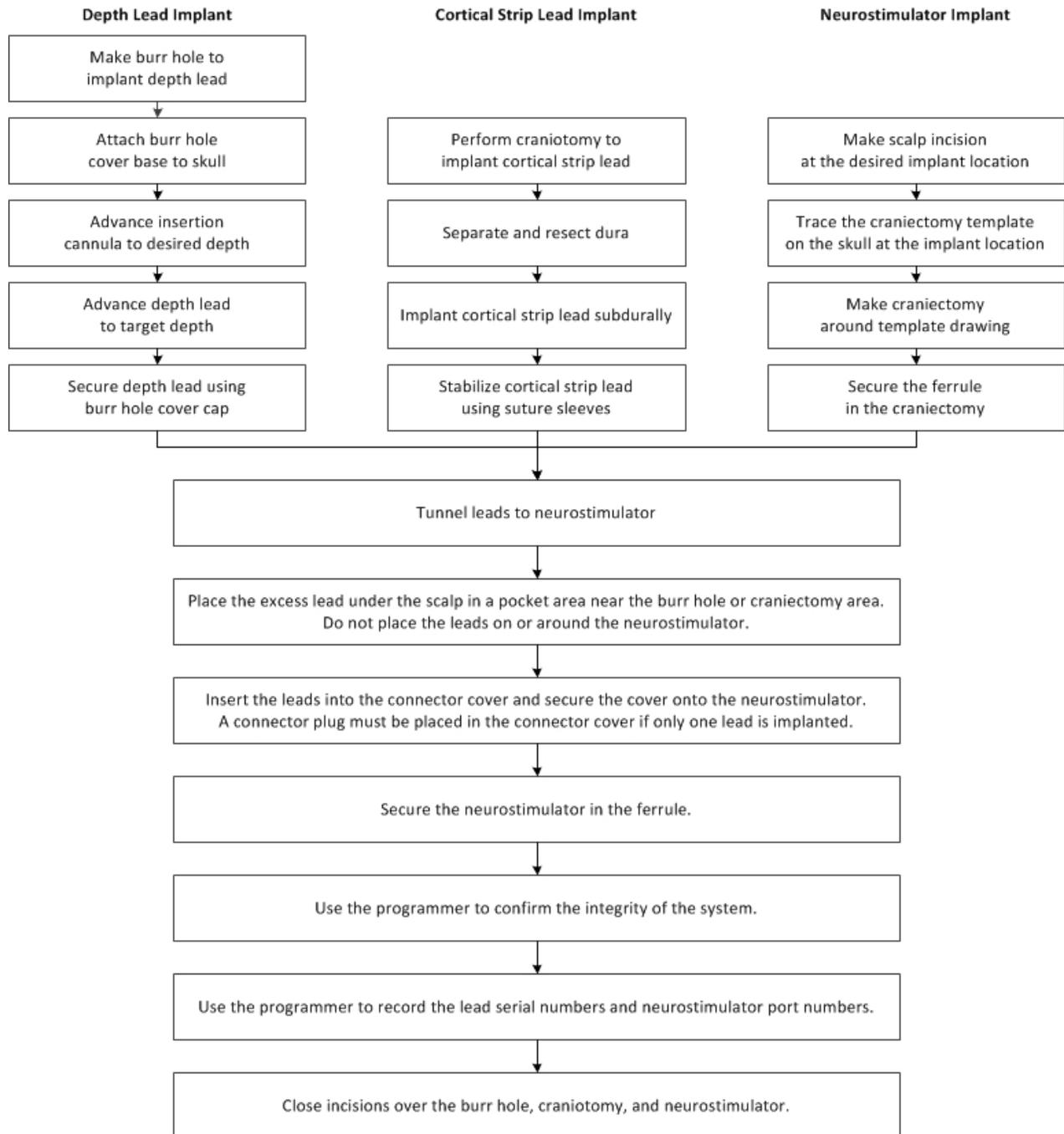
**Figure 5:** Handing the sterile product tray to a surgeon in the sterile field.

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### **Bone Screws**

It is recommended that 1.5 mm diameter, 4 mm long bone screws (not provided) be used to secure the ferrule to the skull. If necessary, 5 mm or 7 mm long bone screws may be used. If the 1.5 mm diameter screws do not securely anchor the ferrule in the skull, 1.8 mm diameter screws should be used.

## RECOMMENDED IMPLANT PROCEDURE FLOW CHART



## RECOMMENDED NEUROPACE® DEPTH LEAD IMPLANTATION AND FIXATION

### Burr Hole Placement

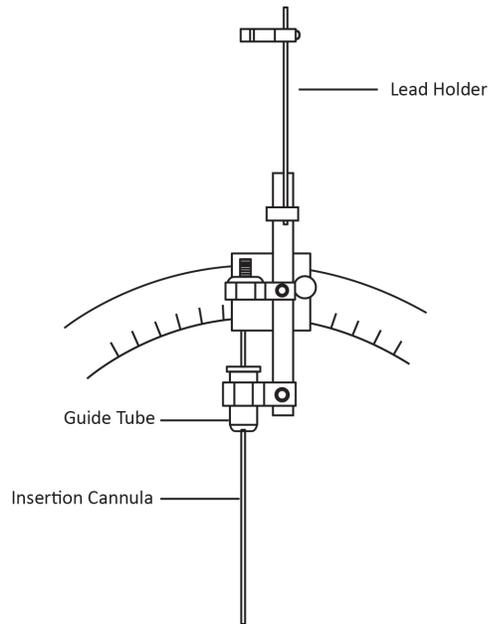
1. Make an incision in the scalp at or near the desired burr hole location.
2. Using a standard perforator, create a 14 mm burr hole in the skull.
3. If using a burr hole cap/cover (not provided), secure the cap base to the skull and follow the manufacturer's instructions for use.

**Note:** It is necessary to consider the distance from the burr hole to the neurostimulator implant site when selecting the appropriate lead length for implantation.

### **Depth Lead Insertion**

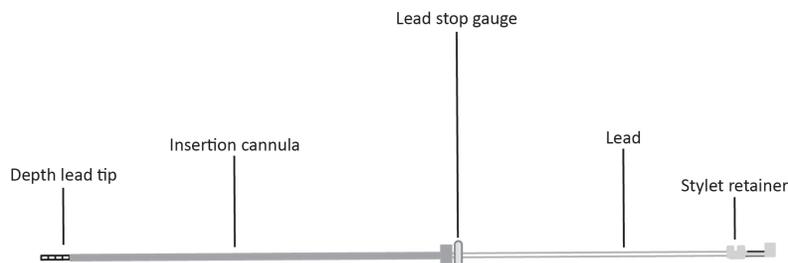
The depth lead may be implanted using standard stereotactic techniques and planning software. The following instructions assume that a stereotactic frame is being used; however other stereotactic methods may be used.

1. Prepare the stereotactic frame for depth lead implantation.



**Figure 6:** Stereotactic frame assembly example.

2. Before placing the insertion cannula onto the frame, insert the depth lead into the insertion cannula and place the stop gauge (provided) on the lead directly above the cannula, such that the lead tip will reach the implant target after the lead is fully advanced down the cannula. The stop gauge should meet the top of the cannula once the lead is advanced the desired distance ([Figure 7](#) on page 28).



**Figure 7:** Position the stop gauge directly above the insertion cannula in order to gauge the full insertion distance of the depth lead.

3. Retract the lead (with stylet and stop gauge intact) from the insertion cannula and set the lead aside.
4. Attach the insertion cannula to the frame.
5. Using standard surgical techniques, prepare the neural tissue for the depth lead implant.

6. Advance the insertion cannula to the desired depth with the insertion cannula stylet in place to seal the insertion cannula lumen. Then remove the insertion cannula stylet and insert the depth lead (with the lead stylet and stop gauge in place) into the insertion cannula.

**Caution: Lead Damage**

Bending, kinking, and stretching of the lead may cause lead damage. Handle the lead with care.

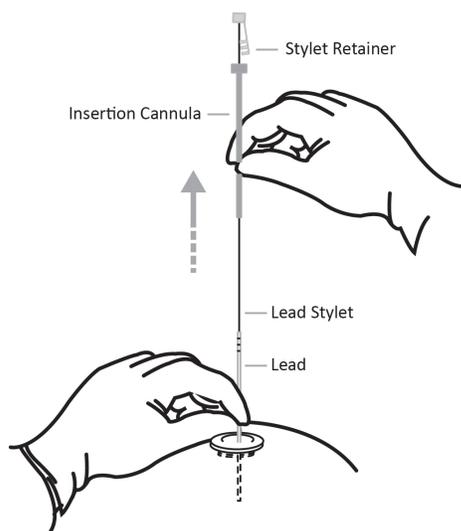
7. Advance the lead into the neural tissue until the stop gauge has reached the top of the insertion cannula.
8. Verify that the lead is in the desired anatomical position.

**Depth Lead Stabilization**

1. Remove the stop gauge and frame components from the lead.
2. While holding the lead in place at the skull, disengage the stylet from the lead by pinching the stylet retainer and gently pulling the stylet away from the lead body.

**Note:** Do not reinsert the stylet into the lead after it has been removed.

3. Gently pull the insertion cannula up over the lead (*Figure 8* on page 29) while stabilizing the lead at the burr hole to avoid lead migration.



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**Figure 8:** Removal of the insertion cannula, stylet, and stylet retainer from the lead.

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4. Leave approximately 10-15 mm of the lead inside the burr hole, allowing slack in the lead before securing the lead to the skull.
5. If using a burr hole cap/cover (not provided), follow the manufacturer's instructions for use for securing the lead to the burr hole.
6. If implanting more than one lead, mark the lead near the proximal lead contacts with a marker (such as non-absorbable sutures) in order to identify the lead.

**Caution: Suture Sleeves**

Suture sleeves are provided for use if sutures are used to stabilize the lead. Suturing directly on the lead may cause lead body damage and malfunction.

7. Place lead caps (provided) on the proximal end of unconnected leads and place the excess lead in a sub-galeal pocket near the burr hole.

**Caution: Sub-Galeal Lead Placement**

Wrapping the lead(s) on/around the neurostimulator, or placing excess lead near the neurostimulator, may result in lead damage during subsequent surgical procedures.

## RECOMMENDED NEUROPACE® CORTICAL STRIP LEAD IMPLANTATION AND FIXATION

### Cortical Strip Lead Insertion

**Note:** The cortical strip lead may be implanted in a manner similar to standard strip lead implants.

1. Make an incision in the scalp at or near the craniectomy location.
2. Perform a craniectomy to insert the strip lead.
3. Separate and dissect the dura around the area of desired cortical strip lead implant.

**Caution: Epidural Lead Placement**

Leads placed epidurally may cause pain during electrical stimulation.

4. Retract or remove the stylet by pinching the stylet retainer, gently pulling the stylet away from the lead body, and then withdrawing the stylet from the lead body the desired distance.
5. Carefully advance the cortical strip lead to the desired location.
6. Verify that the lead is in the desired anatomical position.

### Cortical Strip Lead Stabilization

1. Fully remove the stylet.

**Note:** Do not reinsert the stylet into the lead after it has been removed.

2. Leave approximately 10 mm of the lead inside the craniectomy to allow slack before securing the lead to the skull. Cortical strip leads can be stabilized using the suture sleeves provided in the lead kit. Place the suture sleeve on the lead body at the point where stabilization is desired. Then use non-absorbable sutures to ligate the suture sleeve to the adjacent tissue to stabilize the lead.

**Caution: Suture Sleeves**

Suture sleeves are provided for use if sutures are used to stabilize the lead. Suturing directly on the lead may cause lead body damage and malfunction.

3. Place lead caps (provided) on the proximal end of unconnected leads.

**Note:** If implanting two leads that will not be connected, apply a non-absorbable suture tie to one lead cap to distinguish the unconnected leads. Record the anatomical position of the unconnected leads noting which lead has the non-absorbable suture marker.

**Caution: Sub-Galeal Lead Placement**

Wrapping the lead(s) on/around the neurostimulator, or placing excess lead near the neurostimulator, may result in lead damage during subsequent surgical procedures.

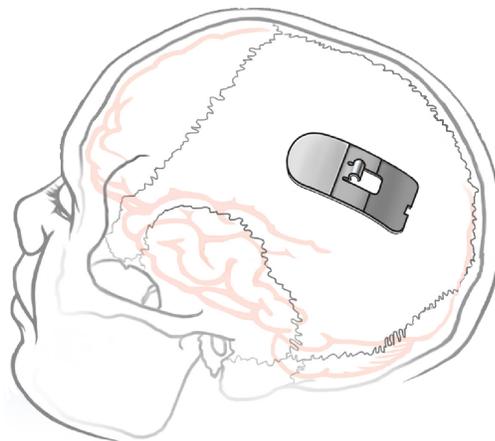
## RECOMMENDED RNS® NEUROSTIMULATOR IMPLANTATION PROCEDURE

### Craniectomy Placement

The recommended location of the neurostimulator is in the parietal skull. However, the neurostimulator may be implanted anywhere in the skull in a position that achieves a good contoured fit and allows the neurostimulator to sit flush with the cranial surface. The neurostimulator can be inserted into the ferrule in only one orientation and the leads exit the connector cover from only one direction. Review the neurostimulator orientation and lead exit point prior to creating the craniectomy.

The location and orientation of the incision line relative to the neurostimulator should be planned to facilitate future neurostimulator replacement. Consider the following:

- The portion of the incision that will need to be reopened to replace the neurostimulator should not traverse the leads.
- The incision should be relatively close to the ferrule clamp and connector cover for ease of access.
- The incision should allow for good exposure of the neurostimulator and the connector cover area if necessary.



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**Figure 9:** Recommended placement of the craniectomy in the skull.

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1. Make a scalp incision at the desired neurostimulator implant location.
2. Trace the craniectomy template on the skull at the implant location.
3. Using a standard perforator, perform a craniectomy around the outside edge of the template tracing.
4. Elevate the perforated portion of the skull to expose the dura.

**WARNING:** Intracranial Hemorrhage

Intracranial hemorrhage may occur when implanting the RNS<sup>®</sup> System. Placing the leads, ferrule, and/or neurostimulator in an area where excess pressure may occur to the underlying blood vessels may cause intracranial hemorrhage. Patients with underlying risk factors for intracranial hemorrhage, such as patients with previous head trauma, anticoagulant use, or who experience head injury with seizures should be taken into specific consideration.

### **RNS<sup>®</sup> Neurostimulator Implantation**

**Note:** The neurostimulator may be implanted and secured in the craniectomy before or after the tunneling of the leads.

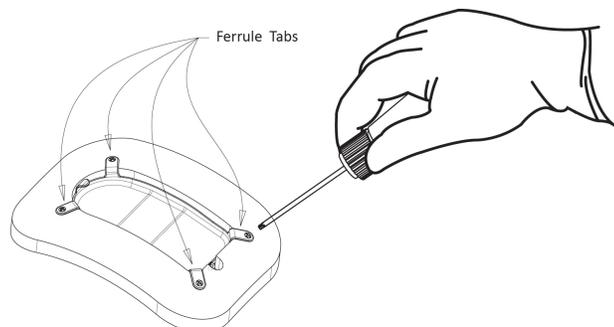
1. Remove bone debris from the areas inside and surrounding the craniectomy.
2. Place the ferrule in the craniectomy. The one prebent ferrule tab can be used as a depth guide for placement of the ferrule.

**Note:** To properly recess the ferrule into the skull, additional bone removal may be required to accommodate the ferrule clamp.

3. Bend the three straight ferrule tabs to the appropriate depth using a needle driver or other surgical instrument.
4. Place the neurostimulator in the ferrule to assess the fit and position. The neurostimulator lead exit point should make a smooth transition to the top of the skull when the neurostimulator is resting in the ferrule.

**Note:** The neurostimulator is packaged with a temporary white cover over the lead contacts. Leave this cover in place until you are ready to attach the leads to protect the contacts during handling.

5. Remove the neurostimulator from the ferrule.
6. Secure the four ferrule tabs to the skull using bone screws (not provided).
7. Partially seat the ferrule clamp in the ferrule using the torque driver to tighten the ferrule clamp screw. Do not fully tighten the ferrule clamp (it should still be able to rotate freely).



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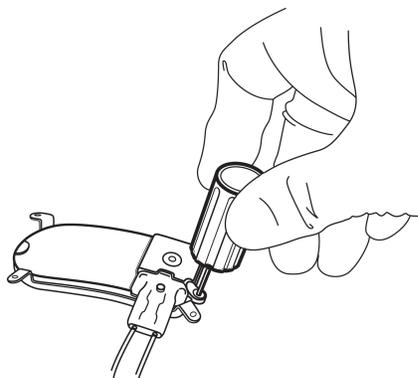
**Figure 10:** The four ferrule tabs secured to the skull with bone screws.

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8. Flush the craniectomy and ferrule.
9. Place the neurostimulator in the ferrule.
10. Rotate the ferrule clamp so that it engages the neurostimulator then fully tighten the ferrule clamp screw until the torque driver clicks (*Figure 11* on page 32).

**Note:** DO NOT use any tools other than the torque driver provided to secure the ferrule clamp in place.



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**Figure 11:** The ferrule clamp securing the neurostimulator to the ferrule.

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**Caution:** Scalp Necrosis

Protrusion of the implanted RNS® System products above the surface of the skull may cause necrosis of the scalp.

## CONNECTING THE RNS® NEUROSTIMULATOR TO THE IMPLANTED LEADS

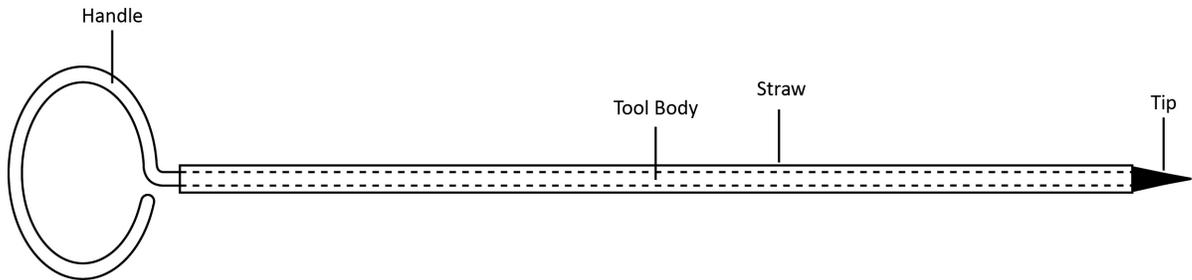
### Tunnel with the Tunneling Tool

1. Remove the temporary cover from the end of the tunneling tool (with tip remaining on the opposite end of the cover).
2. Slide the tunneling tool through the tunneling tool straw.

3. Using the temporary cover as an anchor, screw the tunneling tool tip to the end of the tunneling tool.
4. Remove the temporary cover from the tunneling tool tip.

**Note:** The tunneling tool may be bent to the desired angle.

5. Using the tunneling tool, tunnel under the scalp from the neurostimulator implant site to the lead burr hole.




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**Figure 12:** The tunneling tool is used to tunnel the lead under the scalp from the burr hole to the craniectomy. Advance the tunneling tool under the scalp until the tunneling tool tip exits near the burr hole.

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6. Once the tool has exited the burr hole, unscrew and remove the tip.
7. Slide the tunneling tool handle out from the tunneling tool straw, leaving the straw in place.

**Note:** The tunneling tool straw may be clipped to a shorter length if desired.

8. Gently slide the proximal end of the lead into the tunneling tool straw.
9. Advance the lead from the burr hole to the craniectomy, allowing the proximal lead contacts and lead body to extend from the craniectomy.
10. Remove the tunneling tool straw.

**Note:** Leave sufficient slack in the lead adjacent to skull fixation points to relieve stress on the lead.

#### **Tunnel with Other Tools**

1. Using blunt dissection, create a channel between the lead and neurostimulator positions.
2. Pass the lead under the scalp using the tunneling tool straw (provided).

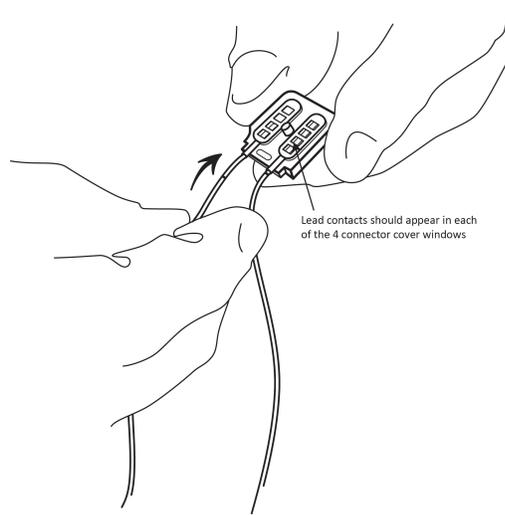
**Note:** The tunneling tool straw may be clipped to a shorter length if desired.

3. Gently slide the proximal end of the lead into the tunneling tool straw.
4. Advance the lead from the burr hole to the craniectomy, allowing the proximal lead contacts and lead body to extend from the craniectomy.
5. Remove the tunneling tool straw.

**Note:** Leave sufficient slack in the lead adjacent to skull fixation points to relieve stress on the lead.

#### **Secure the Neurostimulator and Leads**

1. Hold the connector cover with the windows visible.
2. Place the lead proximal ends into each port of the connector cover until the lead stops.
3. Confirm that the lead marker band is flush with the edge of the connector cover. If there is a gap between the band and the edge of the connector cover seal, gently push the lead into the connector cover port again until the lead stops.
4. Confirm that the lead contacts are fully visible in each window of the connector cover (*Figure 13* on page 34).

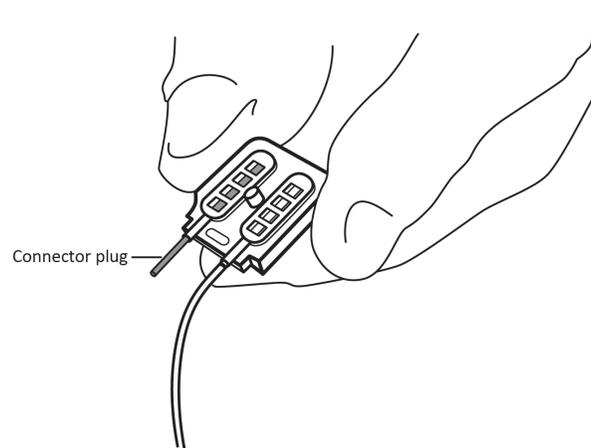


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**Figure 13:** Connector cover with proximal lead contacts in place.

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5. If using only one lead, be sure to place a connector plug in the vacant connector cover port.



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**Figure 14:** Neurostimulator connector cover with a connector plug placed in the one vacant port.

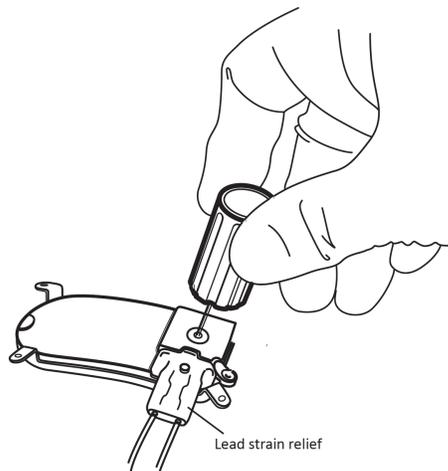
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**Caution:** Connector Plug

A vacant port in the connector cover must be filled with a connector plug (provided in the connector cover kit). There is an increased risk of neurostimulator failure if a connector cover port is vacant.

6. Remove the white temporary connector cover from the neurostimulator.
- Note:** The neurostimulator connector area is extremely fragile and should be handled with care.
7. Flush the neurostimulator connector area to remove debris and dry area before attaching the connector cover.
8. Place the connector cover on the neurostimulator and then loosely attach it to the neurostimulator using the torque driver. Ensure that the leads remain completely inserted in the connector cover.
9. Fully attach the connector cover to the RNS® Neurostimulator by tightening the screw using the torque driver. The torque driver makes a clicking sound when the screw is completely engaged.

**Note:** DO NOT use any tools other than the torque driver provided to secure the connector cover in place.




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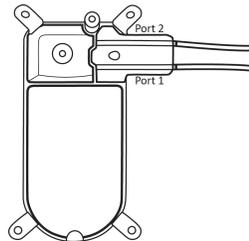
**Figure 15:** Secure the connector cover and leads to the RNS® Neurostimulator using the torque driver.

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10. Place the lead strain relief over the proximal ends of the leads extending from the connector cover ([Figure 15](#) on page 35) and attach it to the post.
11. Cover the wand with a sterile bag and position it over the neurostimulator.
12. Select **INTERROGATE** on the **HOME** screen of the tablet and review the lead impedances (on the **NEUROSTIM INFO** screen) to ensure proper connection between the neurostimulator and the leads. An acceptable range for lead impedance is 250 - 3500 ohms.

If impedance measurements are abnormal, remove the connector cover and flush the connector area. Fully reinsert the leads into the connector cover and repeat the impedance measurements. Refer to [Abnormal Lead Impedance \(greater than 3500 Ohms or less than 250 Ohms\)](#) on page 51 if impedance measurements remain abnormal.

13. Select the lead type for **PORT #1** and **PORT #2** on the **RECORDING MONTAGE** screen of the tablet (refer to [Create the Recording Montage](#) on page 44).




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**Figure 16:** RNS® Neurostimulator Port #1 and #2 locations. Port #1 is located towards the center of the neurostimulator and Port #2 is closer to the edge.

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14. Create the recording montage (assign channels, set gain, and schedule impedance settings) on the **RECORDING MONTAGE** screen of the tablet (refer to [Create the Recording Montage](#) on page 44). **REVIEW & PROGRAM** the information into the neurostimulator.

15. View **LIVE ECoGs** on the **HOME** screen.

If live ECoGs are not adequate, remove the connector cover and flush the connector area. Fully reinsert the leads into the connector cover, repeat impedance measurements, and view **LIVE ECoGs** again.

16. Use the lead caps (provided) to cap the proximal ends of any unconnected leads. Secure the lead caps with a suture if desired.
17. Situate all capped, unconnected leads adjacent to the neurostimulator to facilitate easy connection to the neurostimulator in the future.

18. Place any excess lead length in a sub-galeal pocket near the craniectomy away from the incision line.
19. Close the incision.
20. After the incision closure, interrogate the neurostimulator again using the tablet. Confirm that the impedance measurements and live ECoG signals are normal.

**Note:** It is common for the neurostimulator to reset if electrosurgery is used near the neurostimulator or leads. To recover from a neurostimulator reset perform the following:

1. Document all error messages.
2. Go to the start screen and select **INTERROGATE**.
3. If problems persist, refer to [Troubleshooting](#) on page 51.

## REPLACING OR EXPLANTING THE RNS<sup>®</sup> SYSTEM

### Disposal Guidelines

When explanting any part of the RNS<sup>®</sup> System, the following disposal guidelines are suggested:

- Return the explanted neurostimulator to NeuroPace. Contact NeuroPace to obtain shipping containers.
- Dispose of all product not returned to NeuroPace by adhering to local governing agency recommendations.
- Do not incinerate or cremate the neurostimulator. Explosion may occur when exposed to extreme heat.

### Export and Import Device Settings for Neurostimulator Replacement

The tablet supports the transfer of all device settings from an old to a new neurostimulator as part of a neurostimulator replacement procedure. With the **EXPORT DEVICE SETTINGS** and **IMPORT DEVICE** functions, you can transfer all current neurostimulator settings (recording montage, detection settings, stimulation settings, etc.) to the new neurostimulator.

Export and import are done directly through the tablet without using the PDMS—exported settings are kept locally on the tablet—so no Internet connection is required. This also means that the programmer to which the settings have been exported must be physically present with the new neurostimulator to import settings to the new neurostimulator. This is not usually an issue because export and import are done on the same day: before, during or after the procedure to replace the neurostimulator.

#### **TRANSFER COMPATIBILITY**

You can transfer settings from an RNS-300M to an RNS-300M or to an RNS-320, and you can transfer settings between RNS-320 devices.

**Note:** **SCHEDULED IMPEDANCE** is a new feature in the RNS-320. It allows you to select which electrodes to test for impedance. Since the feature is not present in the RNS-300M, you must select the electrodes to test (and then program) on the new RNS-320 before scheduled impedance works. Its settings are created as part of the recording montage—see [Create the Recording Montage](#) on page 44 for instructions.

#### **EXPORT NEUROSTIMULATOR SETTINGS**

1. Interrogate the old neurostimulator, the one **from** which you will transfer settings.
2. Select the **UTILITIES** (toolbox) icon at upper right of the screen. The **UTILITIES** dialog opens.



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**Figure 17:** Utilities dialog

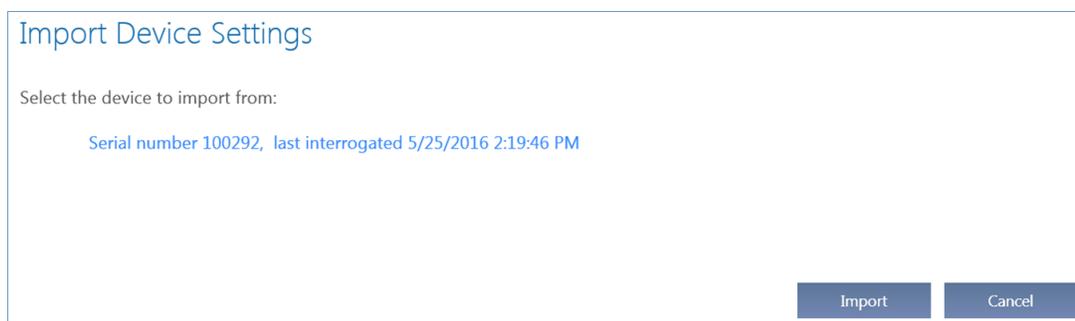
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3. While holding the wand over the neurostimulator, select **EXPORT DEVICE SETTINGS**. You are done. All current neurostimulator settings are stored on the tablet ready for import.

**Note:** The tablet retains only the last device settings exported to it—from any neurostimulator. Every export operation from any neurostimulator overwrites these device settings, if any. Successfully importing and programming the settings from the tablet to a new neurostimulator also deletes these device settings from the tablet.

#### IMPORT NEUROSTIMULATOR SETTINGS

1. Interrogate the new neurostimulator, the one **to** which you will transfer settings.
2. Select the **UTILITIES** (toolbox) icon at upper right of the screen. The **UTILITIES** dialog opens (see the figure above).
3. Select **IMPORT DEVICE**. The **IMPORT DEVICE SETTINGS** dialog appears. It shows the device settings available for import by device serial number and the date and time of last interrogation before the settings were exported to the tablet. It also notifies you if the tablet has no settings that came from a compatible neurostimulator (for example, if you exported from an RNS-320 for use on an RNS-300M).



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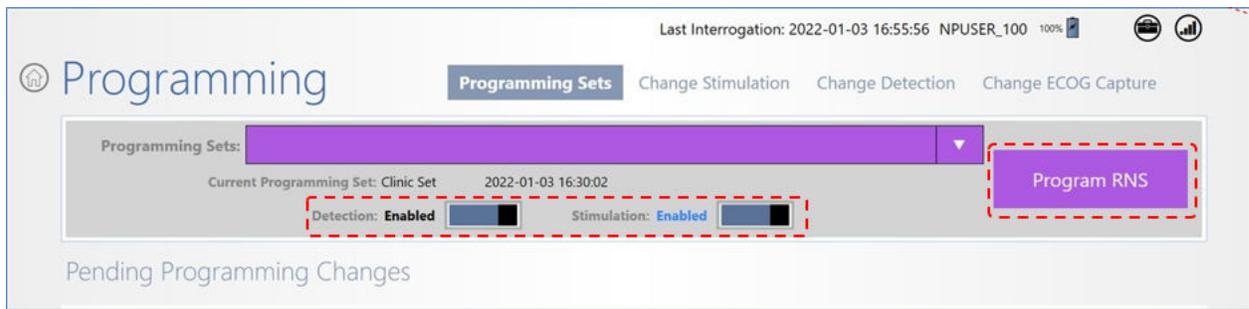
**Figure 18:** Import Device Settings dialog

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**Note:** Device settings can be imported only once because they are deleted from the tablet once you successfully import and select **PROGRAM RNS** from the **PROGRAMMING** screen, as described below.

4. Select the device settings—the selected settings will be highlighted—and then select **IMPORT**. The dialog notifies you that it is importing device settings.

When complete, the tablet **PROGRAMMING** screen opens. The active (purple) **PROGRAM RNS** button indicates pending settings are not yet programmed.



- If you want to enable detection and stimulation at this time, make sure **DETECTION** and **STIMULATION** are set to **ENABLED** at upper center.
5. Place the wand within approximately 1 inch of the neurostimulator and select **PROGRAM RNS**. The **PROGRAMMING NEUROSTIMULATOR** dialog shows programming progress until complete. The imported settings are deleted from the tablet when programming is complete. If you do not complete this step, the settings will remain available on the tablet.

**Note:** After implanting a replacement neurostimulator, monitor the detection behavior. It may be necessary to adjust the detection settings to ensure desired performance. If a bandpass detection tool (**RHYTHMIC ACTIVITY** or **SPIKE ACTIVITY**) is enabled and the settings need to be adjusted, begin by modifying the amplitude settings. See the programming manual for recommended therapy modifications after observing a clinical response.

### Replace the RNS® Neurostimulator with a New Neurostimulator

1. Use the programmer to disable detection and therapy.
2. Verify the position of the leads to avoid damaging the leads during incision. Verification can be performed using prior x-ray or CT imaging.
3. Make an incision in the scalp at the incision line used for the initial neurostimulator implant.

**Note:** It is not necessary to explant the implanted ferrule when replacing the neurostimulator. The ferrule clamp may be replaced.

4. Clear tissue and bone debris away from the area surrounding the neurostimulator and lead strain relief area.
5. Remove the lead strain relief from the neurostimulator and dispose.
6. Use the torque driver to loosen and remove the connector cover.
7. Remove the proximal lead ends from the connector cover.

Make sure the proximal lead ends are appropriately marked so the leads can be connected to correct ports of the new neurostimulator. Dispose of the old connector cover.

#### **Caution:** Lead Damage

Bending, kinking, and stretching of the lead may cause lead damage. Handle the lead with care.

8. Use the torque driver to partially loosen the screw in the ferrule clamp. Swivel the clamp 90 degrees away from the neurostimulator to facilitate removal of the neurostimulator.
9. Remove the neurostimulator from the ferrule.

**Note:** Return the explanted neurostimulator and leads to NeuroPace. NeuroPace will provide shipping containers if requested.

10. Flush the craniectomy and ferrule.
11. Open the new neurostimulator package.

**Note:** The neurostimulator is packaged with a temporary white cover over the lead contacts. Leave this cover in place until you are ready to attach the leads to protect the contacts during handling.

12. Place the new neurostimulator in the ferrule.
13. Secure the neurostimulator to the ferrule by rotating the ferrule clamp into position over the neurostimulator. Tighten the ferrule clamp screw until the torque driver clicks (*Figure 11* on page 32).

**Note:** DO NOT use any tools other than the torque driver provided to secure the ferrule clamp in place.

14. Remove the white temporary cover from the neurostimulator.
15. Flush the neurostimulator connector area (if necessary) to remove debris and dry area before attaching the new connector cover.
16. Hold the new connector cover with the windows visible.
17. Place the lead proximal end into each port of the new connector cover until the leads stop.
18. Confirm that the lead marker band is flush with the edge of the connector cover.

If there is a gap between the band and the edge of the connector cover seal, gently push the lead into the connector cover port again until the lead stops.

19. Confirm that the lead contacts are fully visible in each window of the connector cover (*Figure 13* on page 34).
20. Place the connector cover on the neurostimulator and then loosely attach it to the neurostimulator using the torque driver.

Ensure that the leads remain completely inserted in the connector cover.

**Note:** DO NOT use any tools other than the torque driver provided to secure the connector cover in place.

21. Fully attach the connector cover to the neurostimulator by screwing the cover in until the torque driver clicks.
22. Place the lead strain relief over the proximal ends of the leads extending from the connector cover.
23. If using only one lead, be sure to place a connector plug in the vacant connector cover port.
24. Use the lead caps (provided) to cap the proximal ends of any unconnected leads. Secure the lead caps with a suture if desired.
25. Situate all capped, unconnected leads adjacent to the neurostimulator to facilitate easy connection to the neurostimulator in the future.
26. Place any excess lead length in a sub-galeal pocket near the craniectomy, away from the incision line.

**Note:** Leave sufficient slack in the lead adjacent to skull fixation points to relieve stress on the lead.

27. Cover the wand with a sterile bag and position it over the neurostimulator.
28. Select **INTERROGATE** on the start screen of the programmer and review the lead impedances (on the **NEUROSTIM INFO** screen) to ensure proper connection between the neurostimulator and the leads. An acceptable range for lead impedance is 250 - 3500 ohms.

If impedance measurements are abnormal, remove the connector cover and flush the connector area. Fully reinsert the leads into the connector cover and repeat the impedance measurements. Refer to *Abnormal Lead Impedance (greater than 3500 Ohms or less than 250 Ohms)* on page 51 if impedance measurements remain abnormal.

29. Program the new neurostimulator with the same settings as the explanted neurostimulator.
30. View **LIVE ECoGs** on the start screen.

If live ECoGs are not adequate, remove the connector cover and flush the connector area. Fully reinsert the leads into the connector cover, repeat impedance measurements, and view **LIVE ECoGs** again.

31. Close the incision.
32. After the incision closure, interrogate the neurostimulator again using the programmer. Confirm that the impedance measurements and live ECoG signals are normal.

**Note:** It is common for the neurostimulator to reset if electrosurgery is used near the neurostimulator or leads. To recover from a neurostimulator reset perform the following:

1. Document all error messages.
2. Go to the start screen and select **INTERROGATE**.
3. If problems persist, refer to [Troubleshooting](#) on page 51.

### **Replace the RNS® Neurostimulator with a Cranial Prosthesis**

1. Use the programmer to disable detection and therapy.
2. Verify the position of the leads to avoid damaging the leads during incision.
3. Make an incision in the scalp at the neurostimulator location.

**Note:** It is not necessary to explant the implanted ferrule when replacing the neurostimulator. The ferrule clamp may be replaced.

4. Clear tissue and bone debris away from the area surrounding the neurostimulator and lead strain relief.
5. Remove the lead strain relief from the neurostimulator and dispose.
6. Use the torque driver to loosen and remove the connector cover.
7. Use the torque driver to partially loosen the screw in the ferrule clamp. Swivel the clamp 90 degrees away from the neurostimulator to facilitate removal of the neurostimulator.
8. Remove the neurostimulator from the ferrule.

**Note:** Return the explanted neurostimulator and leads to NeuroPace. NeuroPace will provide shipping containers if requested.

9. Remove the proximal lead ends from the connector cover.

#### **Caution: Lead Damage**

Bending, kinking, and stretching of the lead may cause lead damage. Handle the lead with care.

10. Flush the craniectomy and ferrule.
11. Place the cranial prosthesis in the ferrule.
12. Secure the cranial prosthesis to the ferrule by rotating the ferrule clamp into position over the cranial prosthesis and tightening the ferrule clamp screw until the torque driver clicks.
13. Place proximal lead ends in a sub-galeal pocket.
14. Close the incision.

### **Change Lead Connections**

This section provides instructions for changing which leads are connected to the neurostimulator. The steps found in this section assume the leads are already implanted. In order to change the lead connection, the lead currently connected to the neurostimulator must first be disconnected.

1. Use the programmer to disable detection and therapy.
2. Verify the position of the leads to avoid damaging the leads during incision.

Verification can be performed using prior x-ray or CT imaging.

3. Make an incision in the scalp at the incision line used for the initial neurostimulator implant.
4. Clear tissue and bone debris away from the area surrounding the neurostimulator and lead strain relief area.
5. Remove the lead strain relief from the neurostimulator and dispose.
6. Use the torque driver to loosen and remove the connector cover.
7. Remove the proximal lead ends from the neurostimulator ports and dispose of the old connector cover.
8. Place a lead cap over the proximal contacts of the abandoned leads. The lead caps should be secured with a suture.
9. Flush the neurostimulator connector area (if necessary) to remove debris and dry area before attaching the connector cover.
10. Hold the connector cover with the windows visible.
11. Place the lead proximal end into each port in the connector cover until the leads stop.
12. Confirm that the lead marker band is flush with the edge of the connector cover.

If there is a gap between the band and the edge of the connector cover seal, gently push the lead into the connector cover port again until the lead stops.

13. Confirm that the lead contacts are fully visible in each window of the connector cover (*Figure 13* on page 34).
14. Place the connector cover on the neurostimulator and then loosely attach it to the neurostimulator using the torque driver. Ensure that the leads remain completely inserted in the connector cover.

**Note:** DO NOT use any tools other than the torque driver provided to secure the connector cover in place.

15. Fully attach the connector cover to the neurostimulator by tightening the screw until the torque driver clicks.
16. Place the lead strain relief over the proximal ends of the leads extending from the connector cover and attach it to the post.
17. If using only one lead, be sure to place a connector plug in the vacant connector cover port.

**Caution:** Connector Plug

A vacant port in the connector cover must be filled with a connector plug (provided in the connector cover kit). There is an increased risk of neurostimulator failure if a connector cover port is vacant.

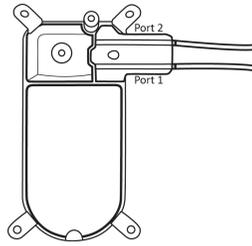
18. Situate all capped, unconnected leads adjacent to the neurostimulator to facilitate easy connection to the neurostimulator in the future.
19. Place any excess lead length in a sub-galeal pocket near the craniectomy, away from the incision line.

**Note:** Leave sufficient slack in the lead adjacent to skull fixation points to relieve stress on the lead.

20. Cover the wand with a sterile bag and position it over the neurostimulator.
21. Select **INTERROGATE** on the **HOME** screen of the tablet and review the lead impedances (on the **NEUROSTIM INFO** screen) to ensure proper connection between the neurostimulator and the leads. An acceptable range for lead impedance is 250 - 3500 ohms.

If impedance measurements are abnormal, remove the connector cover and flush the connector area. Fully reinsert the leads into the connector cover and repeat the impedance measurements. Refer to *Abnormal Lead Impedance (greater than 3500 Ohms or less than 250 Ohms)* on page 51 if impedance measurements remain abnormal.

22. Select the lead type for **PORT #1** and **PORT #2** on the **RECORDING MONTAGE** screen of the tablet (refer to [Create the Recording Montage](#) on page 44).



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**Figure 19:** RNS® Neurostimulator Port #1 and #2 locations. Port #1 is located towards the center of the neurostimulator and Port #2 is closer to the edge.

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23. Create the recording montage (assign channels, set gain, and schedule impedance settings) on the **RECORDING MONTAGE** screen of the tablet (refer to [Create the Recording Montage](#) on page 44). **REVIEW & PROGRAM** the information into the neurostimulator.
24. View **LIVE ECoGs** on the **HOME** screen.
- If live ECoGs are not adequate, remove the connector cover and flush the connector area. Fully reinsert the leads into the connector cover, repeat impedance measurements, and view **LIVE ECoGs** again.
25. Close the incision.
26. After the incision closure, interrogate the neurostimulator again using the tablet. Confirm that the impedance measurements and live ECoG signals are normal.

**Note:** It is common for the neurostimulator to reset if electrosurgery is used near the neurostimulator or leads. To recover from a neurostimulator reset perform the following:

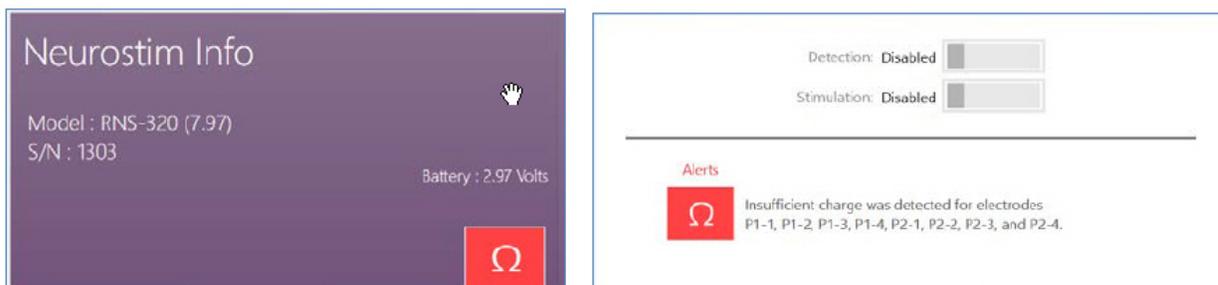
1. Document all error messages.
2. Go to the start screen and select **INTERROGATE**.
3. If problems persist, refer to [Troubleshooting](#) on page 51.

## Programming Instructions

This manual includes limited instructions for use of the tablet during surgical procedures. Refer to the programming manual for the complete set of instructions for the RNS® Tablet (model 5000).

### ELECTRODE IMPEDANCE AND BATTERY VOLTAGE

Interrogation includes measuring electrode impedance and battery voltage, and these measurements are reported on the **NEUROSTIM INFO** screen. The **NEUROSTIM INFO** tile and screen show an alert if the impedance measurement detects insufficient charge for one or more electrodes.



**Figure 20:** Insufficient charge alert shown on the **NEUROSTIM INFO** tile and screen

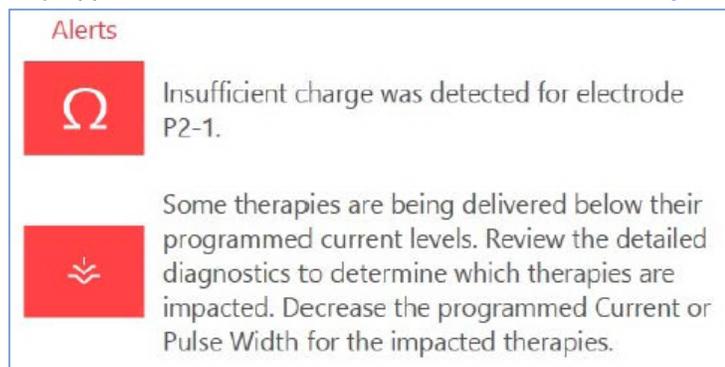
To measure these items again, place the wand within approximately 1 inch of the neurostimulator and select the applicable **MEASURE** button on that screen (select **NEUROSTIM INFO** from the **HOME** screen to get there). For impedance measurements, use the **CURRENT** field to adjust the current delivered during measurement.

**Note:** The system cannot measure impedance during a detected episode or during therapy delivery. To measure impedance, either wait for the episode or therapy to complete, or disable detection and therapy.

### Significance of Impedance

Impedance measurements are useful for verifying the integrity of a particular electrode. Each impedance measurement delivers a single pulse of current between an electrode and the neurostimulator canister (can) to measure the voltage that results as the current flows. Impedance measurements are reported in Ohms (voltage divided by current).

Impedance measurements greater than 3500 Ohms or less than 250 Ohms are considered abnormal. If impedance measurements are abnormally high, there may be insufficient charge to deliver therapy. When this is the case, alerts may appear on the **NEUROSTIM INFO** screen as shown in [Figure 21](#) on page 43.



**Figure 21:** Alerts when there is insufficient charge to deliver therapies.

For troubleshooting information, refer to [Abnormal Lead Impedance \(greater than 3500 Ohms or less than 250 Ohms\)](#) on page 51; and [Insufficient Charge](#) on page 52.

### Significance of Battery Voltage

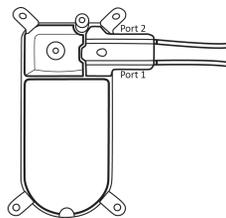
Normal RNS® Neurostimulator battery voltage measurements are between 2.41 and 3.20 Volts. When the battery voltage measurement drops to 2.40 Volts or less, neurostimulator replacement is recommended, and the tablet notifies you on screen by showing the elective replacement indicator (ERI).

### CREATE THE RECORDING MONTAGE

The RNS® Neurostimulator can sense brain activity (ECoGs) from up to four amplifier channels. The programmed configuration of leads and electrodes you assign to each channel constitute the recording montage. You create the montage using the tablet. **Upon initial implant, you must create and program the recording montage to enable all other programming functions. There can be only one current montage and corresponding programming sets. When the montage is altered, the programming sets created with the previous montage become unavailable and a programming set corresponding with the new montage must be programmed.** (Note that if you change the montage to match a prior montage, the programming sets associated with the prior montage become available again.)

### Identifying Ports, Leads and Electrodes on the Neurostimulator

[Figure 22](#) on page 44 identifies neurostimulator **Port #1** and **Port #2** with their leads extending out of the ports.

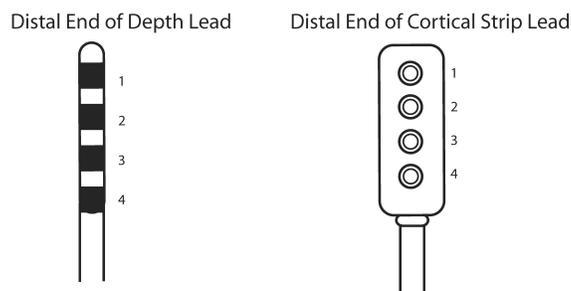


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**Figure 22:** RNS® Neurostimulator port #1 and #2 locations. Port #1 is closer to the center of the neurostimulator and port #2 is closer to the edge.

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For both depth leads and cortical strip leads, the electrodes are numbered 1 through 4 starting from the distal end of the lead.

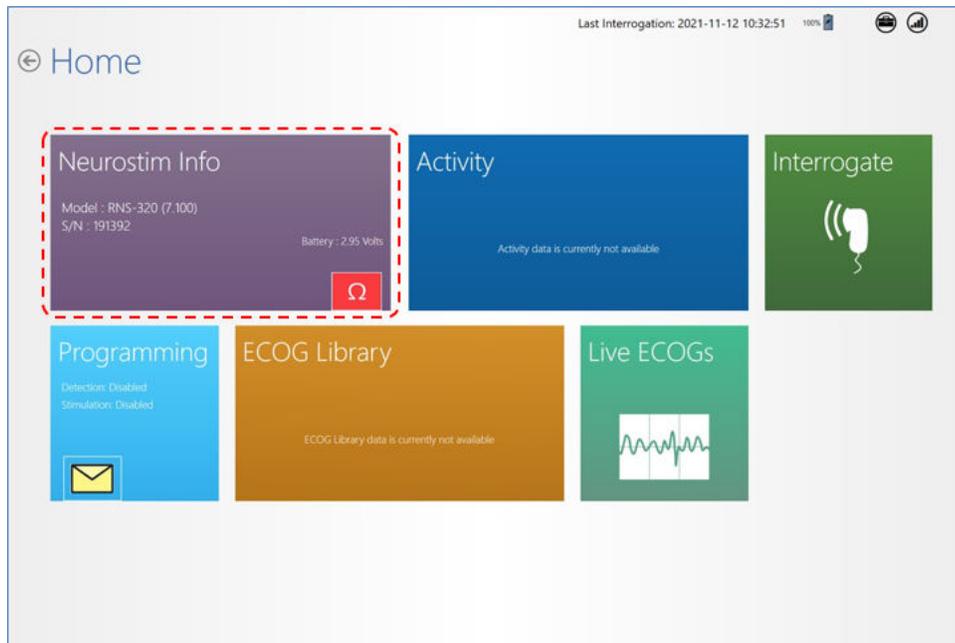


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**Figure 23:** For both lead types, electrodes are numbered 1 through 4. Electrode 1 is the most distal.

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### Creating the Montage



1. From the **HOME** screen, select **NEUROSTIM INFO**. The **NEUROSTIM INFO** screen opens.

**Note:** Changed settings are highlighted blue and new setting text is shown in larger font above the smaller previous setting. Gray or plain items have not changed.



2. On the **NEUROSTIM INFO** screen, select **CHANGE RECORDING MONTAGE** at lower right. The **RECORDING MONTAGE** screen opens.

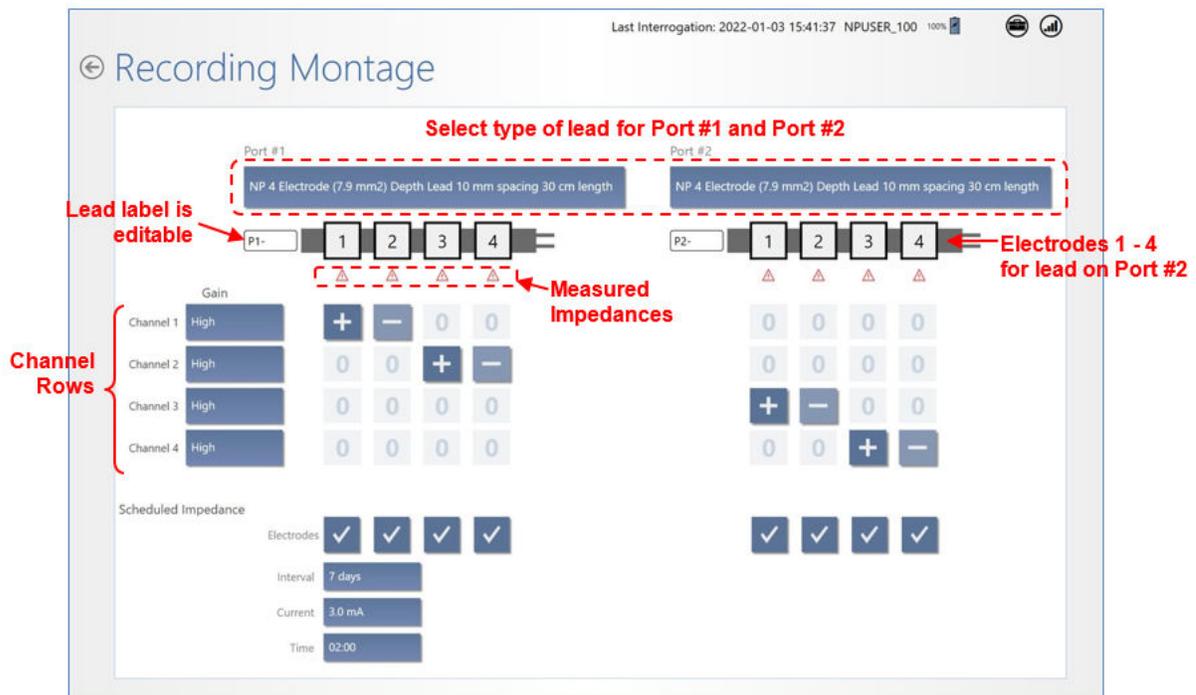


Figure 24: Recording Montage screen

3. **At Neurostimulator Implant and When Changing Leads – Select Lead Type:** Upon first use of leads, you must select the lead type for **PORT #1** and/or **PORT #2**. To do this, select the field that says **NONE**, just below the **PORT #1** or **PORT #2** names at the top, and select the type of lead installed in each port. When lead types are already selected for the ports, proceed to the next step.
4. **Assign Channels:** Use the channel rows and electrode columns to assign two electrodes to each **CHANNEL** (1 through 4). To do this, select the small, square field where the channel and electrode intersect and then select a positive [+] non-inverting input, a negative [-] inverting input, or zero [0]. Sensing occurs across the selected electrodes for each channel.

Each electrode can be assigned to one or two channels, and any electrode assigned to 2 channels must have the same input (+ or -). Use a positive (+) input for an electrode assigned to 2 channels.

**Note:** Using a negative (-) input for electrodes assigned to 2 channels is not advisable as it may result in post-stimulation ECoG artifacts.

5. **Set Gain:** Next to the channel name on the left, select the **GAIN** field for each channel to select **HIGH**, **MEDIUM-HIGH**, **MEDIUM-LOW**, or **LOW**. The default is **HIGH** and it is usually not changed. After programming, you can assess ECoG signal amplification by viewing the live ECoGs.
6. **Scheduled Impedance Settings:** These settings are at lower left. By default, the tablet schedules an impedance test on all electrodes every 7 days with 3.0 mA current at 2:00 AM. Select the fields next to **INTERVAL**, **CURRENT** and **TIME** to choose different settings. Normally there is no need to use other than the default settings.

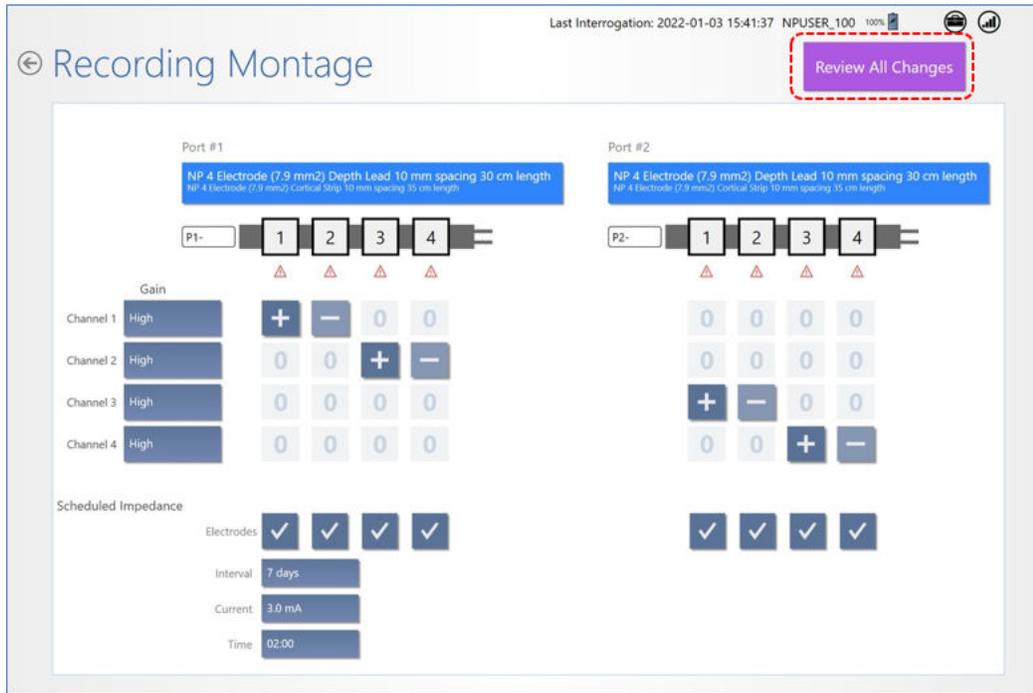
#### Recommended Initial Montage Settings

- **Channel 1** = Lead 1: Electrode 1 [+], Electrode 2 [-]
- **Channel 2** = Lead 1: Electrode 3 [+], Electrode 4 [-]
- **Channel 3** = Lead 2: Electrode 1 [+], Electrode 2 [-]
- **Channel 4** = Lead 2: Electrode 3 [+], Electrode 4 [-]
- **GAIN** set to **HIGH** for all channels (default)
- **SCHEDULED IMPEDANCE** settings = Interval: 7 days, Current: 3.0 mA, Time: 2:00 AM (defaults)

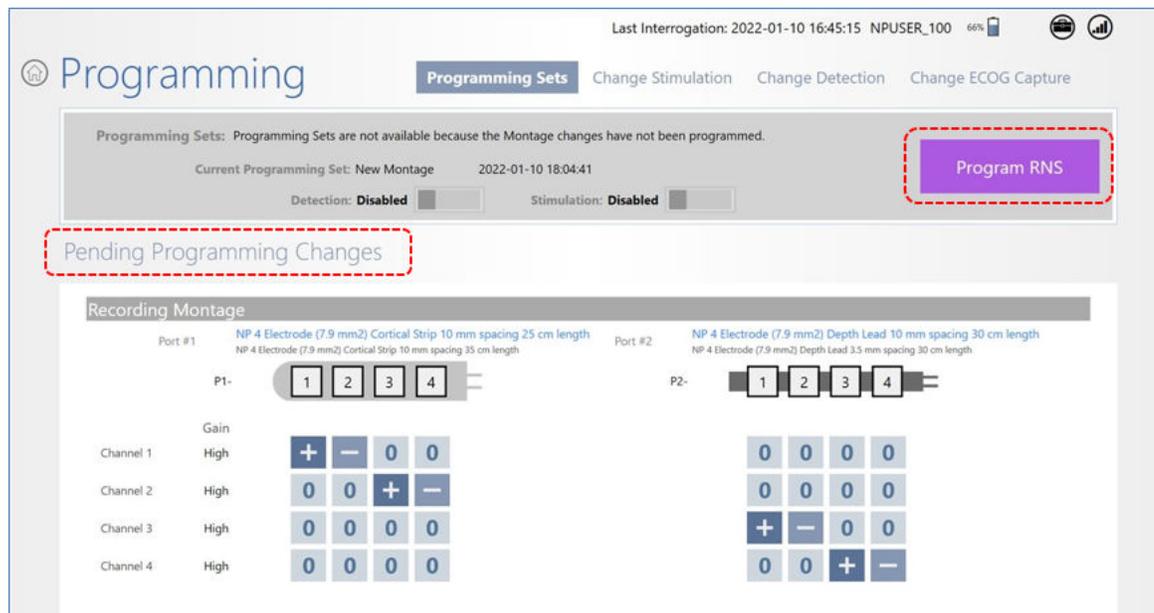
#### Program the Neurostimulator with the New Settings

The new settings are not sent to the neurostimulator until you complete this step.

7. Select **REVIEW ALL CHANGES** at upper right (*Figure 25* on page 47). All **PENDING PROGRAM CHANGES** appear on the **PROGRAMMING SETS** screen (*Figure 26* on page 47) for your review before programming. Scroll down if necessary to see all the changes.



**Figure 25:** Recommended initial montage settings



**Figure 26:** Pending Programming Changes for montage

8. If you are satisfied with the new or changed settings, place the wand within approximately 1 inch of the neurostimulator and select **PROGRAM RNS**. The **PROGRAMMING NEUROSTIMULATOR** dialog shows programming progress.



**Figure 27:** Programming neurostimulator dialog shows progress of programming

When complete, you return to the **PROGRAMMING SETS** screen. The programming set will be named **NEW MONTAGE** with date and time of its creation. You have created the recording montage, which is the prerequisite to create settings for detection, stimulation, and ECoG capture.

## LIVE ECoGs SCREEN

**Note:** You can access the **LIVE ECoGs** screen only after interrogation of the neurostimulator, and the wand must be held within approximately 1 inch of the neurostimulator to acquire live ECoGs.

After interrogation, keep the wand in place and select **LIVE ECoGs** from the **HOME** screen to open the **LIVE ECoGs** screen. An ECoG is live when you open it. Buttons provide various options for viewing the live ECoG. Select **STOP/STORE** to save the ECoG in the patient's ECoG library. It remains on screen after you stop and store it until you start another live ECoG. Captured live ECoGs are stored in the **ECoG LIBRARY** and classified as *User saved*.



**Figure 28:** Live ECoGs screen

Live ECoG capture can be useful for immediate or later analysis of patient ECoGs, for adjusting amplifier gain settings, and for simulated detection. Refer to the programming manual.

**Important:** The recording montage must be programmed before live ECoGs can be viewed. See [Create the Recording Montage](#) on page 44.

**Note:** The maximum length for a live ECoG is four minutes. If the live ECoG is allowed to scroll for more than four minutes, only the last four minutes are stored.

**Note:** Live ECoGs are stored on the tablet, not in the neurostimulator memory, and are uploaded to the PDMS if and when the tablet is connected to the PDMS.

**Caution:** Telemetry Artifact

Telemetry may produce an electrographic artifact. If responsive therapy is enabled with sensitive detection settings, detection of the electrographic artifact may occur, resulting in therapy delivery. The physician should be aware of possible sensing artifacts when assessing the ECoG recordings.

## Magnet

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The magnet suppresses therapy as long as the magnet is held in position over the neurostimulator if the neurostimulator is programmed to do so (default setting). The physician can elect to disable this functionality, whereby magnet placement would have no effect on therapy delivery. Placing or swiping the magnet over the neurostimulator always stores the time of placement in the neurostimulator. This feature can be used to record the time of a patient-determined event, such as when a seizure is starting, and can also trigger ECoG storage if the neurostimulator is programmed to do so. Inform the patient about the proper use of the magnet.

Additional information about the magnet:

- Each time the magnet is placed, the time of placement is stored in the neurostimulator.
- The magnet must be within one inch of the neurostimulator.
- Detection and ECoG storage continue while the magnet is in place.
- When magnet therapy withholding is enabled:
  - Therapy delivery is inhibited only while the magnet is over the neurostimulator.
  - When the magnet is removed, the delivery of therapy resumes as programmed.
  - Test stimulation cannot be delivered while the magnet is in place.
  - Impedance measurements cannot be made while the magnet is in place.

# Troubleshooting

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## DAMAGED PRODUCTS

Inspect NeuroPace products for any damage or breach in package seal integrity. If packaging appears to be wet, punctured, or damaged, contents in package may no longer be sterile. Products with damaged components and/or packaging should not be used and should be returned to NeuroPace for replacement.

## GENERAL TROUBLESHOOTING ACTIVITIES

Problems with the RNS® System may be revealed during an interrogation with the display of an error message on the tablet or through review of lead impedances, battery measurements, or live ECoGs.

If attempts to resolve the problem are ineffective and the problem persists, complete all of the following activities:

- Record all error messages displayed.
- If interrogation of the neurostimulator is possible, complete the interrogation and synchronize the tablet with the PDMS.
- Contact NeuroPace for further assistance.

## ABNORMAL LEAD IMPEDANCE (GREATER THAN 3500 OHMS OR LESS THAN 250 OHMS)

### Troubleshooting During an Intraoperative Procedure

The goal of the following procedures is to ascertain if the abnormal lead impedance measurement is associated with the lead or with the RNS® Neurostimulator port to which the lead is connected.

1. Repeat the impedance measurements.
2. If the impedance remains abnormal, note the electrode label associated with the abnormal impedance.
3. Reconnect leads in the same neurostimulator port.
  - a) Disconnect and reconnect the leads to the connector cover and neurostimulator according to *Noise, Artifacts, Poor Signal Displayed, or No Signal Displayed in Live ECoG* on page 53.
  - b) View the live ECoGs to verify that the signal is sufficient and without noise or artifacts.
  - c) Repeat impedance measurements.
4. If the impedance remains abnormal, note the electrode label associated with the abnormal impedance.
5. Place leads in the opposite neurostimulator port.
  - a) Disconnect leads, place leads in the opposite connector cover ports, and reconnect the connector cover and neurostimulator according to *Noise, Artifacts, Poor Signal Displayed, or No Signal Displayed in Live ECoG* on page 53.
  - b) Program the new lead information and montage and use the same electrode labels for the new lead configuration.
  - c) View the live ECoGs to verify that the signal is sufficient and without noise or artifacts.
  - d) Repeat impedance measurements.

**Note:** If the abnormal impedance is associated with the same electrode label, then the problem may be with the lead.

Depth lead - Impedance > 3500 Ohms

- The depth lead may be damaged and should be replaced. Refer to *Change Lead Connections* on page 40.

Depth lead - Impedance < 250 Ohms

- The depth lead may be damaged and should be replaced. Refer to [Change Lead Connections](#) on page 40.

Cortical strip lead - Impedance > 3500 Ohms

- The high impedance may be due to air.
- Irrigate the area around the cortical strip lead and examine the geometry.
- Repeat impedance measurements.
- If the impedance remains abnormal, the cortical strip lead may be damaged and should be replaced. Refer to [Change Lead Connections](#) on page 40.

Cortical strip lead - Impedance < 250 Ohms

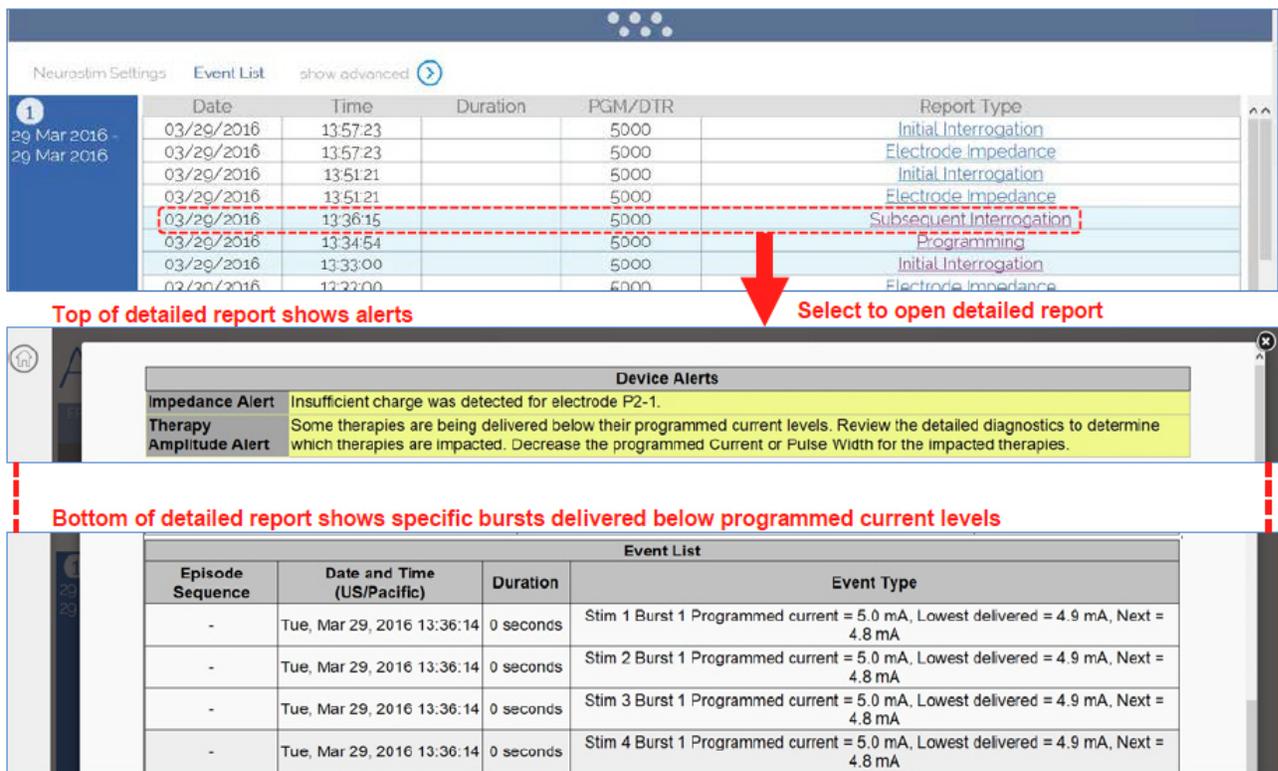
- The cortical strip lead may be damaged and should be replaced. Refer to [Change Lead Connections](#) on page 40.

**Note:** If the abnormal impedance is not associated with the same electrode label, the problem may be with the neurostimulator or connector cover.

6. Replace the connector cover.
  - a) Disconnect the leads from the connector cover and reconnect the leads to a new connector cover.
  - b) Connect to the neurostimulator and troubleshoot according to [Noise, Artifacts, Poor Signal Displayed, or No Signal Displayed in Live ECoG](#) on page 53.
  - c) View the live ECoGs to verify that the signal is sufficient and without noise or artifacts.
  - d) Repeat impedance measurements.
7. If the impedance remains abnormal, replace the neurostimulator. Refer to [Replace the RNS Neurostimulator with a New Neurostimulator](#) on page 38.

## INSUFFICIENT CHARGE

Insufficient charge occurs when the neurostimulator is unable to fully deliver the programmed therapy. It may be due to high lead impedance or the neurostimulator configuration settings. If you receive an insufficient charge alert ([Figure 20](#) on page 43 and [Figure 21](#) on page 43) that cannot be explained by observed lead impedance changes, or if the first entries in the PDMS interrogation report event list show the "Programmed current" is higher than the "Lowest delivered" current, contact your NeuroPace Field Clinical Engineer. The NeuroPace Field Clinical Engineer will help you review the lead impedances and neurostimulator configuration settings to determine the cause. An example interrogation report is shown in [Figure 29](#) on page 53.



**Figure 29:** Accessing an interrogation report that shows insufficient charge

## NOISE, ARTIFACTS, POOR SIGNAL DISPLAYED, OR NO SIGNAL DISPLAYED IN LIVE ECoG

### Troubleshooting During an Intraoperative Procedure

1. If no ECoG signal is seen, make sure lead labels and montage have been programmed.
2. If the signal is too high in amplitude or saturating, decrease the gain setting.
3. If the leads are positioned over the RNS<sup>®</sup> Neurostimulator, move them away from the neurostimulator.
4. Remove the connector cover from the RNS<sup>®</sup> Neurostimulator using the torque driver.
5. Flush the connector cover (with leads inserted) and the RNS<sup>®</sup> Neurostimulator connector area with saline.
6. Remove the leads from the connector cover. Clean the proximal end of the lead with saline and visually inspect that the lead end is free of excess blood or other tissue.
7. Reinsert the leads. Verify that they are fully inserted into the connector cover ports.
8. Place the connector cover back onto the RNS<sup>®</sup> Neurostimulator. Verify, once again, that the leads are fully inserted in the connector cover ports.
9. Secure the connector cover onto the RNS<sup>®</sup> Neurostimulator using the torque driver.
10. View the live ECoGs to verify that the signal is sufficient and free of noise or artifacts. Isolated artifacts may be the result of electrostatic discharge (ESD) or static electricity shocks to the tablet.
11. If the signal contains noise or artifacts, disconnect the AC adapter from the tablet and run on battery power. (Make sure the battery is charged.) Disconnect the network cable as well if it is connected.

12. If the signal is not sufficient, or still contains noise or artifacts, measure the impedances. If the impedances are out of range, follow the instructions in [Abnormal Lead Impedance \(greater than 3500 Ohms or less than 250 Ohms\)](#) on page 51.
13. If impedance measurements are normal, but the problem remains, try using a different tablet, if available.
14. If the problem persists then replace the neurostimulator. Refer to [Replace the RNS Neurostimulator with a New Neurostimulator](#) on page 38.

### **Troubleshooting During a Routine Follow-up**

1. Reposition the wand over the RNS® Neurostimulator and interrogate again.
2. If the signal is not sufficient, follow the instructions in [Poor or No Communication Between the RNS Neurostimulator and the Programmer](#) on page 54.
3. If the signal is not sufficient, measure the impedances. If the impedances are out of range, follow the instructions in [Abnormal Lead Impedance \(greater than 3500 Ohms or less than 250 Ohms\)](#) on page 51.

### **POOR OR NO COMMUNICATION BETWEEN THE RNS® NEUROSTIMULATOR AND THE PROGRAMMER**

1. Confirm that the wand cable is inserted securely into the USB port on the tablet.
2. Confirm that the concave side of the wand faces the neurostimulator and that the wand is within approximately 1 inch of the neurostimulator.
3. Disconnect the AC adapter from the tablet and run on battery power. (Make sure the battery is charged before doing so.) Disconnect the network cable as well if it is connected.
4. Move electronic equipment that may be a source of interference or move away from such equipment if possible. (Turning electronic equipment on and off may help identify the source of any interference.)
  - a) Reposition the wand over the neurostimulator and interrogate.
  - b) View the live ECoGs to verify that the signal is sufficient and void of noise or artifacts.
5. Restart (turn OFF and back ON) the tablet. Attempt the interrogation again.
6. Try a different tablet, if available.
7. Try interrogating a different neurostimulator, if available, to see if the problem is with the neurostimulator.

### **TABLET FREEZES OR DOES NOT TURN OFF**

1. Plug the tablet into a grounded power outlet.
2. Shut down the tablet: Press and hold down the power button for 11 seconds to shut down. Then release the power button and wait 10 seconds.
3. Restart the tablet: Press and hold down the power button for four (4) seconds. After 2-3 seconds, the tablet beeps to indicate it is powering on. If the tablet does not restart, follow these instructions again. If the tablet still does not start, contact NeuroPace for further assistance (see [Contacting NeuroPace®](#) on page 1).

### **TABLET DOES NOT TURN ON**

1. Charge the tablet for at least four (4) hours.
2. Press and hold the power button for four (4) seconds. After 2-3 seconds, the tablet beeps to indicate it is powering on. If the tablet does not turn on, follow these instructions again. If the tablet still does not start, contact NeuroPace for further assistance (see [Contacting NeuroPace®](#) on page 1).

## LOW BATTERY MEASUREMENT

1. Repeat the battery measurement.
2. If interrogation of the RNS® Neurostimulator is possible, complete the interrogation and synchronize the tablet with the PDMS.
3. Contact NeuroPace for further assistance.

## IMPEDANCE MEASUREMENT WAS REJECTED / TEST REQUEST WAS REJECTED

### Message

"Impedance measurement was rejected by the neurostimulator"

"Test request was rejected by the neurostimulator"

### Issue

The neurostimulator cannot perform an impedance measurement or a test stimulation (therapy testing).

### Possible Cause

- The neurostimulator may be delivering therapy. Impedance measurement or test stimulation cannot be performed during responsive therapy.
- The neurostimulator may be detecting an episode. Impedance measurement or test stimulation cannot be performed while an episode is being detected.

### Actions

1. Temporarily disable detection in order to proceed with the test stimulation or impedance measurement; or
2. Wait until the neurostimulator is no longer delivering therapy or detecting an episode.

## RNS® NEUROSTIMULATOR RESET (DC LEAK DETECTED)

### Message

"Neurostimulator SN xxxxxx has reset. Reset Reason: DC leak detected, PC = 49159, Data = 0. Copy the above information exactly for technical support. The neurostimulator will not detect or deliver therapy until it has been programmed. Select Continue and additional information will be gathered on the reset."

### Issue

The neurostimulator has reset. It cannot detect or deliver therapy until it is programmed.

### Possible Cause

A direct current (DC) leak was detected when electrosurgery was performed during surgery.

### Actions

1. Select **CONTINUE**
  - The tablet collects additional information and displays various messages such as "Gather Information Working RAM".
  - The tablet then displays the message: "To recover from the reset condition, continue the interrogation and then program the neurostimulator. Synchronize programmer with PDMS and contact NeuroPace."
2. Select **CONTINUE**
  - The tablet interrogates the neurostimulator, including uploading of any stored ECoGs. The tablet then displays the **SUMMARY** tab.
3. Select the **PROGRAM SETTINGS** tab and select **PROGRAM**.
  - The tablet may display the message: "The neurostimulator contains ECoGs that have not been uploaded to the programmer. Continuing will delete the ECoG data from the neurostimulator. Cancel and interrogate to upload the ECoGs."

**Note:** Any stored ECoGs were already uploaded to the tablet, but they remain stored on the neurostimulator because of the reset.

4. Select **CONTINUE**
  - The neurostimulator is now programmed to the state it was in before the reset occurred.
5. If the reset persistently reoccurs in the absence of any surgical procedures, the neurostimulator may be defective. Contact NeuroPace for further assistance.

## Specifications and Characteristics

### RNS<sup>®</sup> SYSTEM SPECIFICATIONS AND CHARACTERISTICS

**Table 4: RNS<sup>®</sup> Neurostimulator (Model RNS-320)**

Width	28 mm 42 mm (including lead strain relief)
Length	60 mm
Thickness	7.7 mm 8.5 mm (including lead strain relief)
Weight	17.2 g 19.2 g (including connector cover and lead strain relief)
Volume	11 cc
Material	Titanium
X-Ray Identification	RNS-320
Operating Temperature	14 °C to 42 °C
Number of Output Channels	Up to 8 electrodes (4 per lead) and the neurostimulator can are selectable for use in stimulation
Connector Retention Strength	0.9 lbs
Waveform	Biphasic
Pulse Shape	Rectangular
Pulse Width Per Phase	40 µsec – 1000 µsec (user selectable)
Current/Voltage Regulated	Current regulated
Max Output Current at Neurostimulator with Battery Voltage at EOS (Output limited to 12.0 mA by tablet):	
500 Ohms	12.0 mA ± 10%
800 Ohms	12.0 mA ± 10%
1200 Ohms	10.0 mA ± 10%
Max Output Voltage at	
500 Ohms	6.0 V ± 10%
800 Ohms	9.6 V ± 10%
1200 Ohms	12.0 V ± 10%
Frequency	1 to 333 Hz 3 to 1000 msec p-p interval
Burst Duration	10 msec to 5 seconds
Charge Imbalance	< 10 µC/sec (at 50 Hz, 5 mA and 120 µsec/phase)
Leakage Current (No Output)	< 0.5 µA
Maximum Charge Density	25 µC/cm <sup>2</sup> (limited by programmable selections)

Pulse Delivery Mode	Burst
Pulse Per Burst	1 to 1666 pulses
Current Path Options	Bipolar or Multipolar
Battery Life	For medium stimulation and detection settings the battery is estimated to last 10.8 years (see <a href="#">RNS Neurostimulator Longevity</a> on page 17)
Interval Between ERI and EOS	3 Months
Voltage at ERI	2.40 V
Voltage at EOS (Minimum Average)	2.30 V

**Table 5: RNS® System Wireless**

Wireless Function	Transfer data between the neurostimulator and the tablet or remote monitor and wand: interrogation, programming and live ECoGs
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 6: Programmer Wi-Fi Specifications**

<b>Table 1 WiFi Specifications Dell Model 5285 and 5290 Model: T17G Reg Type No: T17G001 and T17G002 FCC ID N7NEM7455-D7</b>	
Frequency Band	2400-2483.5 MHz
Type	WLAN 2.4 GHz
Class	DTS
Modulation	DSSS
Effective Radiated Power	10.7 dBm
Frequency Band	5150-5850 MHz
Type	WLAN 5.0 GHz
Class	NII
Modulation	OFDM
Effective Radiated Power	13.96 dBm
<b>Table 2 WiFi Specifications Dell Model 7200 Model: T04J Reg Type No: T04J001 FCC ID MCL T77W968-D2</b>	
Frequency Band	2400-2483.5 MHz
Type	WLAN 2.4 GHz
Class	DTS
Modulation	DSSS
Effective Radiated Power	14.28 dBm
Frequency Band	5150-5850 MHz
Type	WLAN 5.0 GHz
Class	NII
Modulation	OFDM
Effective Radiated Power	14.15 dBm
<b>Table 3 WiFi Specifications Dell Model 7320 Contains FCC ID MCLT77W968-D10 Contains FCC ID PD9AX201D2</b>	
Frequency Band	2400-2483.5 MHz
Type	WLAN 2.4 GHz
Class	DTS
Modulation	DSSS
Effective Radiated Power	24.23 dBm
Frequency Band	5150-5850 MHz
Type	WLAN 5.0 GHz

Class	NII
Modulation	OFDM
Effective Radiated Power	24.24 dBm
<b>Table 4 WiFi Specifications Dell Model 7350 Contains FCC ID E2K BE200D2 Contains FCC ID E2K T99W373PC15</b>	
Frequency Band	2400-2483.5 MHz
Type	WLAN 2.4 GHz
Class	DSS
Modulation	DSSS
Effective Radiated Power	25.46 dBm
Frequency Band	5150-5850 MHz
Type	WLAN 5.0 GHz
Class	NII
Modulation	OFDM
Effective Radiated Power	28.46 dBm

**Table 7: RNS® System Leads**

	Cortical Strip Leads	Depth Leads
Lengths	15 cm, 25 cm, and 35 cm	30 cm and 44 cm
Lead Body	Isodiametric	Isodiametric
Distal End	1 x 4 array	1 x 4 array
Lead Body Diameter	1.27 mm	1.27 mm
Number of Electrodes	4	4
Electrode Spacing Available	10 mm	3.5 mm and 10 mm
Conductor Resistance (± 10%)	15 Ohms for 15 cm lead 25 Ohms for 25 cm lead 35 Ohms for 35 cm lead	30 Ohms for 30 cm lead 44 Ohms for 44 cm lead
Lead Body Material	Silicone	Silicone
Electrode Material	Platinum / Iridium	Platinum / Iridium
Coil Material	Platinum / Iridium	Platinum / Iridium
Stylet Material	Tungsten, Parylene coated	Tungsten, Parylene coated
Stylet Retainer Material	Nylon	Nylon

**Table 8: Implantable Component and Accessory Materials**

Component or Accessory	Material
Connector Cover	Polyaryletheretherketone / Titanium
Connector Plug	Silicone
Cranial Prosthesis	Titanium
Ferrule	Titanium
Ferrule Clamp	Polyaryletheretherketone / Titanium
Lead Cap	Silicone
Lead Strain Relief	Silicone
Suture Sleeve	Silicone

**Table 9: RNS® Tablet, Model 5000**

Dimensions*	Width: 29 cm Height: 21 cm Depth: 1 cm
Material	Commercial Materials
Weight*	0.86 kg
Power Source	100 – 240 VAC, 1.7 A or internal rechargeable battery
USB Power Supply	5 V, 500 mA
Operating Temperature	32 to 104 °F (0 to 40 °C)

\* Typical, approximate values. The values for your tablet may be different.

**Table 10: 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 programmer or remote monitor
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

## 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 in this section.

The neurostimulator is intended to sense electrical activity of the brain, detect activity of interest, deliver stimulation therapy, and communicate with a programmer. In addition, the neurostimulator is intended to operate autonomously, conserve battery life, check for proper connectivity to leads, and automatically recover from certain conditions.

Electromagnetic disturbances may be detected by the neurostimulator as noise or saturation and therefore suppress the ability of the neurostimulator to detect activity of interest during the exposure to the electromagnetic field. Conversely, electromagnetic disturbances may be detected as activity of interest and result in the delivery of programmed stimulation to the patient. Electromagnetic disturbances will not cause the neurostimulator to change modes or operating parameters. Electromagnetic disturbances will not cause the neurostimulator to exceed prescribed therapy limits or charge density limits. Electromagnetic disturbances can be expected to reduce the ability of the neurostimulator to communicate with the programmer. If this happens, refer to *Poor or No Communication Between the RNS Neurostimulator and the Programmer* on page 54. The neurostimulator is expected to recover all intended functions following the removal of the electromagnetic disturbance.

### Hospital or Medical Environments

Patients should always inform healthcare personnel that they have an implanted RNS® System (and show their 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 *Warnings and Cautions* on page 3 for specific information.

### Home, Work, or Public Environments

The patient should avoid or exercise caution when in the presence of the following potential sources of EMI that may affect the operation of the neurostimulator system:

- Radiofrequency identification (RFID) sources
- Airport security and other surveillance systems
- Power lines and transmission towers
- Electric substations, power generators, and large transformers
- Portable and mobile RF communications equipment
- Electric arc welding equipment
- Electric steel furnaces
- Electric induction heaters
- Electric fences
- Body fat measurement scales
- Jackhammers
- Stun guns

The following commonly used items should not affect the operation of the neurostimulator:

- Cell phones and Bluetooth devices
- Electric toothbrushes, electric shavers, and hair trimmers
- Microwave ovens
- Appliances such as washing machines, dryers, electric stoves, toasters, blenders, electric can openers, and food processors
- Electric blankets and heating pads
- Personal computers, electric typewriters, copiers, and fax machines
- Televisions, AM/FM radios, stereos, personal music players

- Vacuum cleaners and electric brooms

For additional information about devices that generate electromagnetic interference contact NeuroPace (see [Contacting NeuroPace®](#) on page 1). If a patient suspects EMI is disrupting the operation of their neurostimulator, advise the patient to 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, 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 programmer with wand is designed for use in a medical environment by a trained healthcare professional. 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 11: Guidance and manufacturer's declaration – electromagnetic emissions – for all equipment and systems**

<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment – guidance</b>
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 <sup>1</sup>	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	

<sup>1</sup> Tablet (model 5000) and Remote Monitor (models 5100 and 5106) tested for harmonic emissions and flicker. Other products excluded from harmonic emissions and flicker testing.

**Table 12: Guidance and manufacturer's declaration – electromagnetic immunity – for all equipment and systems**

Immunity test	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact discharge <sup>1</sup> ± 2, 4, 8, 15 kV air discharge <sup>1</sup>	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 <sup>2</sup>	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 <sup>3</sup>	
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	0% U <sub>T</sub> 0.5 cycle 0% U <sub>T</sub> 1 cycle <sup>4</sup> 40% U <sub>T</sub> 5 cycles <sup>4</sup> 70% U <sub>T</sub> 25 cycles 0% U <sub>T</sub> 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 A/m <sup>5</sup>	

<sup>1</sup> 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).

<sup>2</sup> Immunity to electrical fast transients tested with Tablet (model 5000), Remote Monitor (models 5100, 5106).

<sup>3</sup> Immunity to surge line to earth tested with Programmer (model PGM-300), Remote Monitor (models DTR-300-E, 5106).

<sup>4</sup> Immunity to voltage dips with compliance to 0% U<sub>T</sub> 1 cycle for Tablet (model 5000) and Remote Monitor (models 5100, 5106) and to 40% U<sub>T</sub> 5 cycle for Programmer (model PGM-300) and Remote Monitor (model DTR-300-E).

<sup>5</sup> Power frequency magnetic immunity tested with Tablet (model 5000), Remote Monitor (models 5100, 5106) and Wand (model W-02) to 30 A/m.

**Table 13: 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 <sup>1</sup> 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.  <b>Recommended separation distance</b> <sup>2, 3</sup>
Radiated Immunity (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz <sup>5</sup>	$d = 1.17\sqrt{P}$ (80 MHz to 800MHz)
Proximity fields from RF wireless communications equipment (IEC 61000-4-3) <sup>6</sup>	See next table below footnotes.	$d = 2.33\sqrt{P}$ (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 magnetic fields (IEC 61000-4-39) <sup>7</sup>	8 A/m, 30 kHz 65 A/m, 134.2 kHz 2.1 kHz PM 7.5 A/m, 13.56 MHz 50 kHz PM	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>4</sup> , should be less than the compliance level in each frequency range.  Interference may occur in the vicinity of equipment marked with the following symbol: 

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> Proximity fields from RF wireless communications equipment tested with Remote Monitor (model 5106)

<sup>7</sup> Proximity field magnetic immunity tested with Wand (model W-02).

**Table 14: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment--see Proximity fields from RF wireless communications equipment in table above**

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 + 5kHz 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 15: Recommended separation distances between portable and mobile RF communications equipment and the RNS® System<sup>1, 2, 3</sup>**

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

<sup>1</sup> 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.

<sup>2</sup> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>3</sup> 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.

## System Products, Components, Accessories, and Tools

### RNS® NEUROSTIMULATOR KITS

Table 16: Model RNS-320-K Contents

Item	Model Number
RNS® Neurostimulator	RNS-320
Connector Cover	CC-01
Ferrule	F-01
Ferrule Clamp	FC-01
Lead Strain Relief	LSR-01
Torque Driver	TD-01

Table 17: Model RNS-300M-K Contents

Item	Model Number
RNS® Neurostimulator	RNS-300M
Connector Cover	CC-01
Ferrule	F-01
Ferrule Clamp	FC-01
Lead Strain Relief	LSR-01
Torque Driver	TD-01

### NEUROPACE® CORTICAL STRIP LEAD AND NEUROPACE® DEPTH LEAD KITS

Table 18: Models CL-315-10-K, CL-325-10-K, and CL-335-10-K Contents

Item	Model Number
NeuroPace® Cortical Strip Lead	CL-315-10, CL-325-10, CL-335-10
Lead Cap (2)	LC-01
Suture Sleeve (4)	SS-01
Tunneling Tool Straw	TTS-01

**Table 19: Models DL-330-3.5-K, DL-330-10-K, DL-344-3.5-K, and DL-344-10-K Contents**

Item	Model Number
NeuroPace® Depth Lead	DL-330-3.5, DL-330-10, DL-344-3.5, DL-344-10
Lead Cap (2)	LC-01
Stop Gauge	SG-01
Suture Sleeve (4)	SS-01
Tunneling Tool Straw	TTS-01

## SURGICAL ACCESSORY KITS

### NeuroPace® Lead Accessory Kit

**Table 20: Model LA-02-K Contents**

Item	Model Number
Lead Cap (2)	LC-01
Suture Sleeve (4)	SS-01
Stop Gauge	SG-01
Tunneling Tool	TT-01
Tunneling Tool Tip	TTT-01
Tunneling Tool Straw	TTS-01

### Craniectomy Template Kit

**Table 21: Model CT-01-K Contents**

Item	Model Number
Craniectomy Template	CT-01
Lead Strain Relief	LSR-01
Torque Driver	TD-01

### Connector Cover Kit

**Table 22: Model CC-01-K Contents**

Item	Model Number
Connector Cover	CC-01
Connector Plug (2)	CP-01
Lead Strain Relief	LSR-01
Torque Driver	TD-01

**Cranial Prosthesis Kit**

**Table 23: Model P-01-K Contents**

Item	Model Number
Cranial Prosthesis	P-01
Ferrule Clamp	FC-01
Torque Driver	TD-01

**Ferrule Kit**

**Table 24: Model F-01-K Contents**

Item	Model Number
Ferrule	F-01
Ferrule Clamp	FC-01
Torque Driver	TD-01

**Explant Kit**

**Table 25: Model EX-01-K Contents**

Item	Model Number
Lead Cap (2)	LC-01
Torque Driver	TD-01

**RNS® TABLET KITS**

**Table 26: Model 5001 Contents**

Item	Model Number
RNS® Tablet (with attached case)	5000
AC Adapter	
Carrying Bag	
Used with	
Wand	W-02

**NEUROPACE® REMOTE MONITOR KITS**

**Table 27: Model 5101 Contents**

Item	Model Number
NeuroPace® Remote Monitor (Laptop)	5100
Ethernet Cable (Network Cable)	
Carrying Case	PC-01
Used with	
Wand	W-02

**Table 28: Model 5107 Contents**

Item	Model Number
NeuroPace® Remote Monitor (Tablet)	5106
Carrying Bag	
Used with	
Wand	W-02

**Table 29: Model 5104 Remote Monitor Phone Accessories Contents**

Item
External Modem
Telephone Cord
Telephone Splitter

**Table 30: Model DTR-300-E-K Contents**

Item	Model Number
NeuroPace® Remote Monitor	DTR-300-E
Ethernet Cable (Network Cable)	
Carrying Case	PC-01
Used with	
Wand	W-02

**Table 31: Model DTR-300-K Contents**

Item	Model Number
NeuroPace® Remote Monitor	DTR-300
Telephone Cord	
Telephone Splitter	
Carrying Case	PC-01
Used with	
Wand	W-02

**Table 32: Model M-01 Contents**

Item	Model Number
Magnet	M-01

## Glossary

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### **Adapt Channel**

The adapt channel is an advanced responsive therapy setting. The neurostimulator will monitor this channel from which to calculate the adaptive stimulation frequency. This channel is used for all adaptive bursts.

### **Adapt Min Amplitude**

The percentage of the detected signal amplitude to be used as the minimum therapy amplitude.

### **Adaptation**

The neurostimulator may be programmed to deliver the pulse interval for a responsive therapy burst by adapting to the electrographic signal by a selected percentage.

### **Anode**

The positive pole of an electrode selected for stimulation.

### **Area Detection Tool**

The area detection tool measures the area under the curve of an ECoG signal.

### **Asynchronous Pulse**

Delivery of the first pulse in a burst independent of the ECoG activity.

### **Bandpass Detection Tool**

The bandpass detection tool measures the approximate frequency of the signal based on the duration and amplitude of waveform segments.

### **Battery Measurement**

The neurostimulator battery voltage may be measured interactively through the programmer.

### **Burr Hole**

Hole made in the skull used for the insertion and securing of implanted cortical and/or depth leads.

### **Burr Hole Cap**

The burr hole cap is intended to secure the leads in relation to the cranium.

### **Burr Hole Cover**

The burr hole cover is intended to secure the leads to the burr hole cap.

### **Burst**

An individually programmed group of one to many pulse(s) of current delivered by the neurostimulator.

### **Burst Duration**

The amount of time during which a burst will be delivered by the neurostimulator.

### **Burst 1**

The first burst of stimulation delivered within an individual responsive therapy. This burst may be delivered asynchronously or synchronously.

### **Burst 2**

The second burst of stimulation delivered within an individual responsive therapy. This burst may be programmed ON or OFF for each therapy and will always be delivered asynchronously following Burst 1 of the therapy if programmed ON.

**Calculated Charge Density**

The charge density of a selected and/or programmed stimulation is calculated by the programmer. Charge densities greater than 25  $\mu\text{C}/\text{cm}^2/\text{phase}$  are not allowed to be selected or programmed into the neurostimulator.

**Can**

“Can” is used to describe the neurostimulator titanium body. The can may be used as either an anode (+) or cathode (-) in a stimulation pathway.

**Cathode**

The negative pole of an electrode selected for stimulation.

**Channel**

The amplifier channel of electrodes selected to detect ECoG activity.

**Connector Cover**

The connector cover is intended to secure the proximal lead contacts and lead strain relief to the body of the neurostimulator.

**Connector Cover Port**

The connector cover ports contain the point of contact between the proximal end of the lead(s) and the neurostimulator. The connector cover contains two (2) ports, one for each lead.

**Connector Plug**

The connector plugs are used to fill any ports on the connector head of the neurostimulator that are not in use.

**Cortical Strip Lead**

The NeuroPace<sup>®</sup> Cortical Strip Lead lies on the surface of the brain (cortex) and can detect the electrical activity of the brain and deliver stimulation.

**Cranial Prosthesis**

The cranial prosthesis is intended to occupy the vacant craniectomy after the neurostimulator has been explanted.

**Craniectomy**

Defect formed in the skull in order to implant the neurostimulator.

**Craniectomy Template**

The craniectomy template is intended to be used as a pattern to mark and delineate the shape of the ferrule on the skull prior to making the craniectomy.

**Current**

The amplitude of current that will be delivered in each phase of a current pulse.

**Default Therapy Frequency**

The default therapy frequency is an advanced setting available for each responsive therapy burst. For an adaptive therapy burst (Adaptation = ON), if the calculated stimulation frequency does not fall between the programmed min and max frequencies, then the stimulation is delivered at the default therapy frequency.

**Delay**

A programmed delay in the delivery of the first pulse of a burst, measured from the time of synchronizing to a signal peak.

**Depth Lead**

The NeuroPace® Depth Lead is implanted into the brain and can detect the electrical activity of the brain and deliver stimulation.

**Detection Settings**

Settings that combine patterns and detection tool settings in order to detect activity.

**Detection Tools**

There are three (3) types of detection tools selectable for Pattern A or Pattern B detectors. The detection tools are: the bandpass tool, power change tool (also known as the line length tool), and area tool.

**ECoG**

Electrocorticogram. Electrical activity derived directly from the cerebral cortex. Also used to describe the neurostimulator or programmer stored record of this activity (e.g. "ECoG record").

**ECoG Activity**

ECoG activity refers to activity which is detected by the neurostimulator using one of the event detectors.

**ECoG Trigger**

The type of neurostimulator activity selected by the user to result in the capture of an ECoG record if the activity occurs.

**Elective Replacement Indicator (ERI)**

The ERI indicator is displayed on the programmer to notify the user that the neurostimulator is approximately three months prior to end-of-service (EOS). Neurostimulator elective replacement is suggested at a battery voltage equal to the ERI.

**End-Of-Service (EOS)**

End of service is the point in service at which the battery level is still sufficient to allow operation, however some features may be lost.

**Event**

Activity detected by the neurostimulator. Events are considered any of the following: long episodes, pattern A, pattern B, responsive therapy, noise, or saturation.

**Ferrule**

The ferrule is intended to be installed in a craniectomy to secure and mechanically support the neurostimulator in the cranium.

**Ferrule Clamp**

The ferrule clamp is used to secure the neurostimulator to the ferrule.

**Frequency**

The frequency is the rate at which pulses are delivered which is expressed in Hz (pulses/second).

**Gain**

ECoG signal amplification on one channel of the neurostimulator.

**Impedance Measurement**

The opposition of current flow between electrodes as determined by measuring the voltage (Ohms) resulting from the delivery of a current pulse. A current pulse must be applied to the patient in order to obtain this measurement.

**Interrogate**

The act of retrieving stored data and settings from the neurostimulator using the programmer.

**Lead Cap**

The lead cap is intended to physically protect the proximal ends of implanted leads that are not connected to the neurostimulator.

**Lead ID**

Numerical and/or alpha characters assigned to a lead to describe its anatomical location.

**Lead Strain Relief**

The lead strain relief is intended to mechanically support the proximal ends of the lead at their exit point from the neurostimulator.

**Line Length Detection Tool**

See Power Change Detection Tool. The line length detection tool (also known as the power change detection tool) performs an estimate of the length dimension of a signal related to the complexity of a signal.

**Live ECoG**

ECoG data viewed in real-time through the programmer.

**Long Episode**

Initiate ECoG storage when a detected episode continues beyond a preset duration.

**Magnet**

The magnet can be used by a patient to mark a clinical seizure, and depending on how the physician programs the neurostimulator, to trigger electrocorticographic (ECoG) storage and withhold therapy.

**Max Therapy Frequency**

The max therapy frequency is an advanced setting available for each responsive therapy burst. For an adaptive therapy burst (Adaptation = ON), the max therapy frequency specifies the maximum stimulation frequency. If the calculated stimulation frequency does not fall between the programmed min and max frequencies, then the stimulation is delivered at the default therapy frequency.

**Min Therapy Frequency**

The min therapy frequency is an advanced setting available for each responsive therapy burst. For an adaptive therapy burst (Adaptation = ON), the min therapy frequency specifies the minimum stimulation frequency. If the calculated stimulation frequency does not fall between the programmed min and max frequencies, then the stimulation is delivered at the default therapy frequency.

**Montage**

Collective term used to describe the assignment of electrode labels and gain settings to the amplifier channels.

**Neurostim Info**

Programmer display of measurements of the neurostimulator lead impedances and battery voltage.

**Neurostimulator**

The RNS<sup>®</sup> Neurostimulator is an implantable, battery powered, microprocessor controlled device that can amplify and analyze the patient's electrocorticographic activity, detect activity from intracranial electrodes and deliver a short train of current pulses to the brain to attempt to interrupt the detected activity.

**Noise**

1. An event detector that identifies 60 Hz noise from selected detection channels. 2. Environmental interference in the telemetry between the neurostimulator and wand/programmer.

## Overwritten

Once the memory for ECoG or diagnostics is full, the neurostimulator will store new data by overwriting the oldest ECoG records or diagnostics. Reserved ECoGs are only overwritten by newer ECoGs of the same ECoG capture trigger type.

## Patient Data Management System (PDMS)

The NeuroPace® Patient Data Management System is a secure database that provides a means for a clinician to review information that has been transmitted by the programmer and the remote monitor.

## Pattern Detection

Analysis of detection settings using the programmer detection tools and retrieved neurostimulator ECoG records.

## Patterns

Patterns (pattern A and pattern B) use a collection of detection tools to classify electrographic activity. Patterns A1 and B1 apply to the first chosen channel and Patterns A2 and B2 to the second chosen channel.

## Post-Episode Interval

Responsive therapies will be DISABLED for this period of time after detecting the end of an episode.

## Power Change Detection Tool

The power change detection tool (also known as the line length detection tool) performs an estimate of the length dimension of a signal related to the complexity of a signal.

## Programmer

The programmer provides the clinician with a user interface to select and download operating parameters to the neurostimulator for detection and responsive stimulation settings, to view live ECoG signals, to test the RNS® System integrity, and to upload data and diagnostic information from the neurostimulator for viewing.

## Programming

Using the programmer to program settings into the neurostimulator.

## Programming Set

A programming set includes the settings for detection, stimulation, and ECoG capture.

## Pulse

A biphasic waveform of electrical stimulation delivered by the neurostimulator.

## Pulse-Width Per Phase (PW)

Duration of a single phase within a biphasic pulse, measured in milliseconds.

## Reset

When the neurostimulator resets, detection and all therapies are disabled, and the neurostimulator stops storing ECoGs and diagnostics. (However, events prior to reset will be saved.) If you interrogate a neurostimulator that has reset, the programmer displays one or more alerts that describe the cause of the reset. When the type of reset is recoverable, the programmer displays instructions to recover, which typically guide you to reprogram the neurostimulator. If the reset is not recoverable, or if recovery is unsuccessful, note the cause of the reset and contact NeuroPace (see [Contacting NeuroPace®](#) on page 1).

## Responsive Stimulation

Electrical stimulation output to cortical tissue by the RNS® Neurostimulator in response to a detection.

**Saturation Event Detector**

Saturation occurs when an input signal exceeds the dynamic range of a particular channel. The neurostimulator incorporates a saturation detector to reduce occurrences of detecting saturation as a neurological event.

**Scheduled Storage**

A selectable neurostimulator function that causes the neurostimulator to capture an ECoG at the desired time(s) of day.

**SimpleStart Feature**

This feature allows the physician to easily begin the process of defining detection parameters by touching or clicking on the location in the ECoG where the physician would like detection to occur.

**Simulate Performance**

Simulation uses the programmer to test a proposed set of detection settings with retrieved ECoGs. The simulation will generate markers, simulating how the neurostimulator may detect if those settings are programmed into the neurostimulator.

**Start Time**

Scheduled storage setting controlling the time(s) at which ECoG capture will be triggered.

**Stereotactic Frame**

A medical device that is attached to the patient's head and provides a three-dimensional frame of reference for accurate implantation of depth leads.

**Stereotactic Surgery**

Surgery in which a system of three-dimensional coordinates is used to locate the site to be operated on.

**Stim Pathway**

Collective term describing the anodes (+) and cathodes (-) selected for a burst.

**Stop Gauge**

The stop gauge is placed on a depth lead prior to implantation to indicate the appropriate depth of its insertion.

**Stylet**

Support wire contained in both the cortical strip and depth leads. The stylet is removed after proper lead placement has been achieved.

**Suture Sleeve**

The suture sleeve is intended to protect the lead body at the point at which the lead is sutured to subcutaneous tissue to immobilize it and prevent its dislodgement while chronically implanted.

**Synch Channel**

The neurostimulator will monitor this channel for ECoG signal peaks to calculate synchronous delivery timing. One channel will be used for all bursts selected to have synchronous pulse delivery.

**Synchronization**

Delivering the first pulse in a burst or after a first pulse delay (Synchronous) from a peak in an ECoG signal.

**Technical Parameters**

Option to configure detection using all detection parameters.

**Telemetry**

Communication between the neurostimulator and the programmer.

**Test Stimulation**

A stimulation that is configured and delivered in real-time using a programmer.

**Therapy Frequency Multiplier**

Therapy frequency multiplier is an advanced responsive therapy setting. The therapy frequency multiplier specifies the ratio of the stimulation frequency to the sensed signal frequency.

**Therapy Limit Per Day**

Responsive therapy delivery will be DISABLED for the remainder of the day after the programmed number of responsive therapies has been delivered.

**Therapy Sequence**

Responsive therapy is delivered as a therapy sequence of up to 5 individually configured sequential therapies (electrical stimulation) in response to each detected episode.

**Tunneling**

Part of the implant procedure during which the proximal end of an implanted lead is tunneled from the burr hole location to the neurostimulator implant location to achieve a lead/neurostimulator connection.

**Tunneling Tool**

The cranial tunneling tool is intended to tunnel implanted leads from their point of exit from the cranium through a sub-galeal pathway to the implanted neurostimulator location.

# Index

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## A

Afterdischarge activity [8](#)

## B

Battery

Low Measurement [55](#)

Burr hole [27](#)

## C

Candidates for the RNS System [20](#)

Cautions

Afterdischarge activity [8](#)

Electronic interference [10](#)

Heating [10](#)

Placement of the programmer power cord [10](#)

Programmer Failure [8](#)

Telemetry Artifact [9](#), [49](#)

Change Lead Connections [40](#)

Contacting NeuroPace [1](#)

Contraindications

Diathermy [2](#)

Electroconvulsive Therapy (ECT) [2](#)

Transcranial Magnetic Stimulation (TMS) [2](#)

Cortical Strip Lead

Stabilization [30](#)

Creating the Recording Montage [44](#)

## D

Depth Lead

Insertion [28](#)

Stabilization [29](#)

## E

Electronic interference [10](#)

Emissions and Immunity Information [63](#)

Export and Import Device Settings for Neurostimulator

Replacement [36](#)

Export Device Settings - neurostimulator replacement [36](#)

Export Neurostimulator Settings [36](#)

## F

FCC Information [iii](#)

## I

Import Device Settings - neurostimulator replacement [36](#)

Import Neurostimulator Settings [37](#)

Incompatibility with other medical devices [10](#)

Indication [2](#)

Interference, RFID [5](#)

## L

Leads

Change Connections [40](#)

## M

Magnet [50](#)

Montage - Create [44](#)

## N

neurostimulator replacement - export and import device settings [36](#)

## P

Patient training [21](#)

Poor or No Communication Between Neurostimulator and Programmer [54](#)

Potential Shock Warning [6](#)

power cord placement [10](#)

Programmer Description [15](#)

Programmer failure [8](#)

## R

replacement procedure - export and import device settings [36](#)

RFID Interference Warning [5](#)

RNS Neurostimulator Programmer [15](#)

RNS Tablet [15](#)

## S

Specifications and Characteristics [57](#)

Symbols [iv](#)

## T

Tablet Does Not Turn On [54](#)

Tablet Freezes or Does Not Turn Off [54](#)

Telemetry Artifact [9](#), [49](#)

Toolbox icon - Utilities [36](#)

Transfer Compatibility [36](#)

Troubleshooting poor communication with neurostimulator [54](#)

Troubleshooting Tablet Does Not Turn On [54](#)

Troubleshooting Tablet Freezes [54](#)

## U

Utilities (toolbox) icon [36](#)

## W

Warnings

NeuroPace Components [6](#)

NeuroPace Equipment Placement [6](#)

Portable and Mobile Radio Frequency (RF)

communications equipment [6](#)

Potential Shock [6](#)

RFID Interference [5](#)

Security and Electronic Tracking Systems [5](#)

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