



The RNS[®] System

Clinic Workflow and Programming

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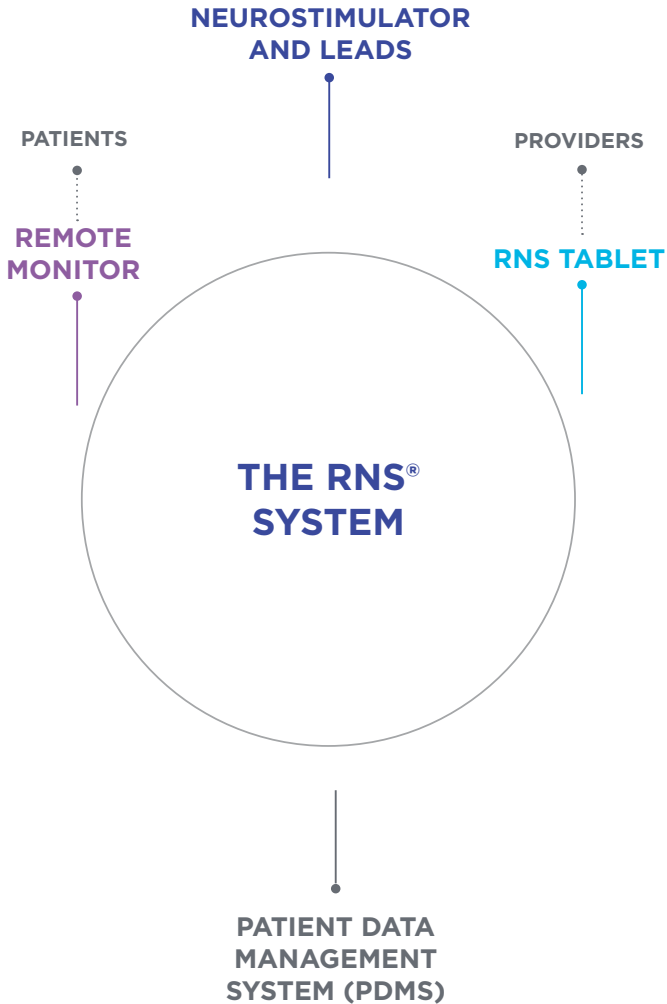
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01



RNS SYSTEM OVERVIEW





01. RNS SYSTEM OVERVIEW



NEUROSTIMULATOR AND LEADS

- The neurostimulator is an **implantable device** that senses and records **ECoG patterns** and is programmed to deliver **electrical stimulation** upon detection of patient-specific patterns.
- There are **two types of leads** that can be implanted at the seizure focus: **cortical strip leads** and **depth leads**. Each lead has four electrodes for sensing and stimulation.



PATIENT DATA MANAGEMENT SYSTEM (PDMS)

- Secured online **database of patient and product data** that can be accessed through the **RNS® Tablet** or any **personal computer/mobile device** connected to the internet.
- Authorized users are granted access through a **qualified user name and password**.

RNS® TABLET



- A tablet computer and wand with **proprietary software** used to communicate with and program the **RNS Neurostimulator**.
- Authorized centers are granted a **single RNS Tablet user name and password** for all users.

REMOTE MONITOR



- The remote monitor consists of a laptop computer with a **proprietary software program, a wand, and accessories** that allow patients to **collect data** from the neurostimulator and send it to PDMS.

02



LOGIN

RNS TABLET INTERFACE

1. Connect to the internet.
2. Login to the RNS Tablet using your **shared center login name.**



3. Login to PDMS using your **personal credentials.**



INTERNET INTERFACE

1. Connect to the internet
www.neuropace.com/PDMS
2. Login to PDMS using your **personal credentials.**



3. Select patient from patient list.



4. PDMS Home Screen will appear.



Click on patient list

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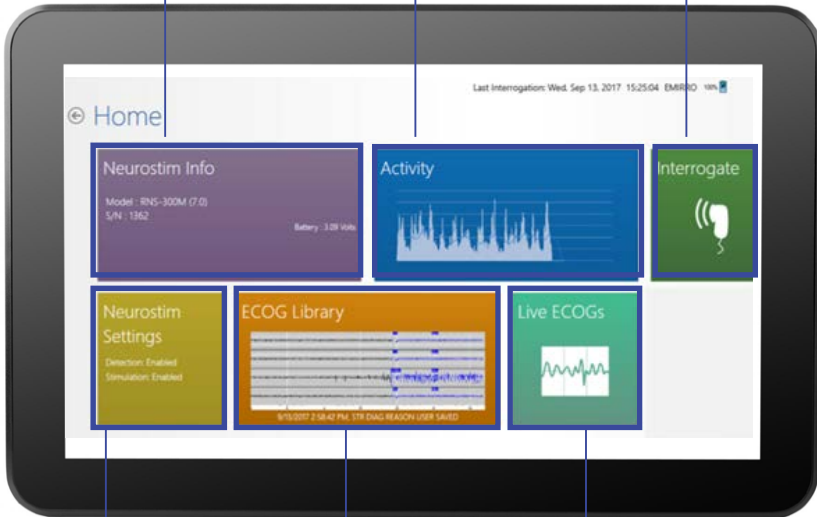


HOME SCREEN OVERVIEW

Review vital information about the RNS neurostimulator and leads and enable/disable detection and stimulation.

Review detection and stimulation settings used over time.

Retrieve data from the RNS neurostimulator.



Program stimulation settings, create detection sets, and establish ECOG capture criteria (See the **appendix** for ECOG trigger definitions).

Review database of patient ECOGs that have been captured by the RNS Neurostimulator.

Use wand to view and/or save a real-time ECOG during a patient visit.

04



RNS CLINIC WORKFLOW



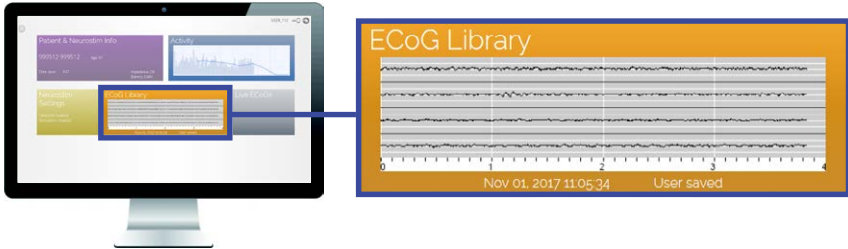


BEFORE PATIENT VISIT

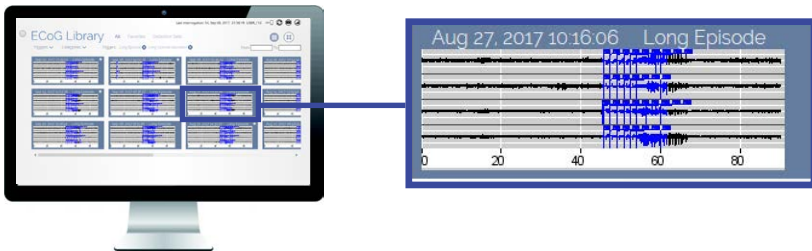
- Access PDMS from RNS tablet or personal computer (see **login**) and navigate to Home screen.

STEP 1: REVIEW ECoGs

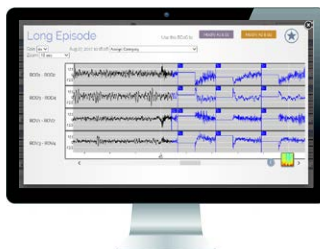
1. Click on the “ECoG Library” tile.



2. Select a thumbnail to open it in a larger size. Detected activity appears in blue. Colored flags mark specific points of detection (A1, B1, etc.) or stimulation (Tr).

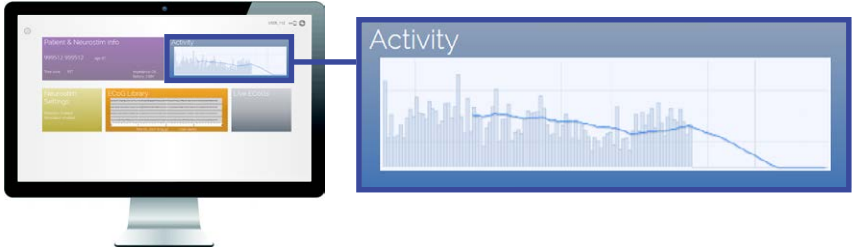


3. Review captured electrographic seizures to ensure ictal onsets are promptly detected. Review scheduled ECoGs to ensure normal baseline activity is not detected.



STEP 2: REVIEW ACTIVITY

1. Click on the “Activity” tile.



2. Review Detection History: use histogram view.



3. View specific events of interest: Click on left or right axis to view a drop list to select which types of events are displayed. This can include long episodes, pattern A, pattern B, responsive therapy, noise or saturation.



4. View specific time periods of interest: Select the magnifying button in upper right corner. Click and drag across histogram to review the time period of interest.



5. Review previously programmed settings by clicking and dragging up on the six dots at the bottom of the screen.

- The table in the lower section shows programmed settings for each time period with the most recent settings at the top.
- Changes from prior settings are indicated by blue shading.
- Clicking on one of the rows in the table will highlight the date range where those settings were programmed.

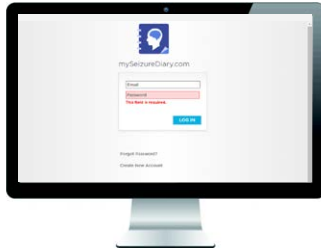




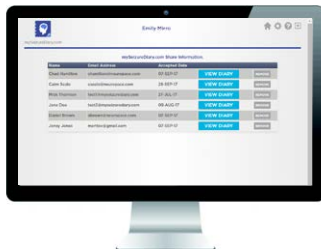
04. RNS CLINIC WORKFLOW

STEP 3: REVIEW SEIZURE DIARY*

1. Login to www.mySeizureDiary.com



2. Select patient from patient list (access must be granted by patient, via email).



3. Review clinical seizure and health/quality of life changes logged since last visit.



*While mySeizureDiary.com is a validated site for logging seizure frequency and health data, there are other platforms with which to achieve this task. It is of utmost importance to establish a baseline before treatment and then track patient performance throughout treatment.



04. RNS CLINIC WORKFLOW

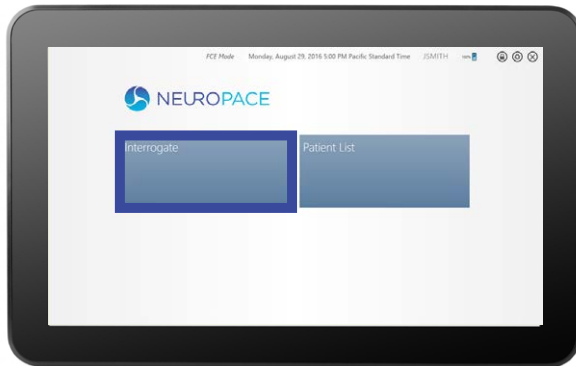


DURING PATIENT VISIT

- Power on and login to RNS Tablet and to PDMS (see **login**).

STEP 4: INTERROGATE

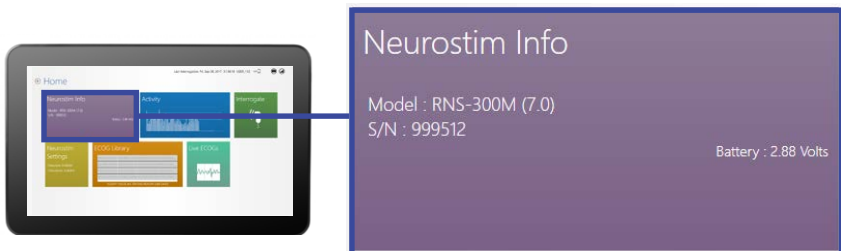
1. Connect wand to RNS Tablet USB port.
2. Place wand 1 inch from Neurostimulator and select “Interrogate” on RNS Tablet.



3. Keep wand in the same position until interrogation is complete.

STEP 5: VERIFY NO ALERTS

1. Confirm there are no alerts on the “Neurostim Info” screen.





04. RNS CLINIC WORKFLOW

MOST COMMON ALERTS:



Pending Detection Set Alert – signifies that a detection set has been sent to this RNS Tablet. Navigate to NeuroStim Settings to review/program the detection set.



Low Battery Alert – patient needs to be scheduled for replacement.

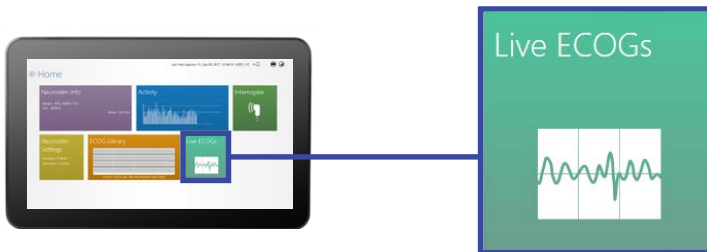


Impedance Irregularity Alert – contact your NeuroPace representative for more information on the potential root cause.

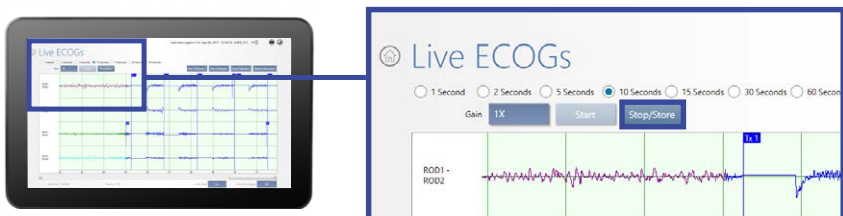
2. If other alerts are found, or if you have any questions or concerns, please contact your NeuroPace Representative.

STEP 6: REVIEW LIVE ECoG

1. After interrogation, keep the wand in place and select “Live ECoGs” from the Home screen to review ECoG.



2. Stop/Store Button: Saves ECoG in patient’s ECoG Library, classified as User Saved.

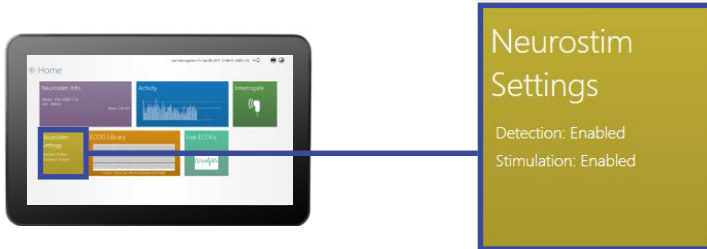




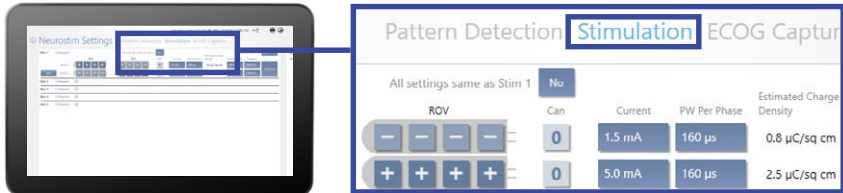
STEP 7: MAKE ADJUSTMENTS & PROGRAM, IF NECESSARY

A. CONFIGURE STIMULATION

1. Go to “NeuroStim Settings” from the Home screen.

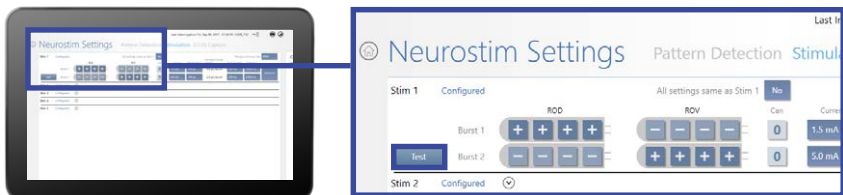


2. Select “Stimulation” in the center of the page.



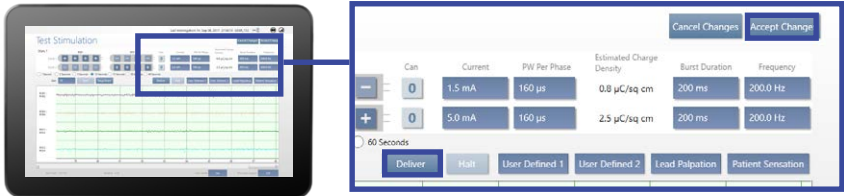
3. Configure, using the recommended settings.

4. Select “Test” to open Test stimulation screen to ensure stimulation is well tolerated by the patient and that there are no undesired changes in the ECoG.



5. Select “Deliver” to deliver a test burst to ensure the patient does not feel stimulation and that after-discharges do not occur.

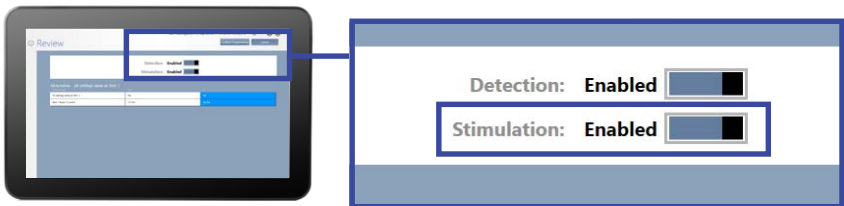
6. Select “Accept Changes”.



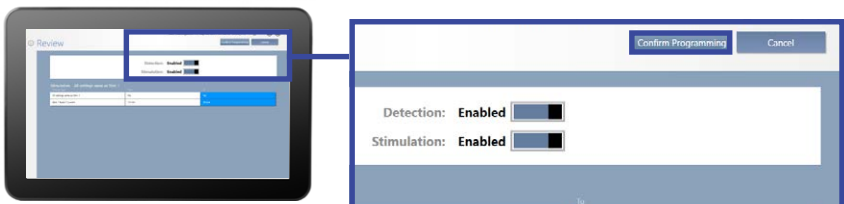
7. Enable Stimulation by selecting “Review and Program” upper right corner.



8. Make sure stimulation is enabled on the next screen.



9. Place wand over RNS and select “Confirm Programming.” Hold the wand in place until the screen shows programming is complete.





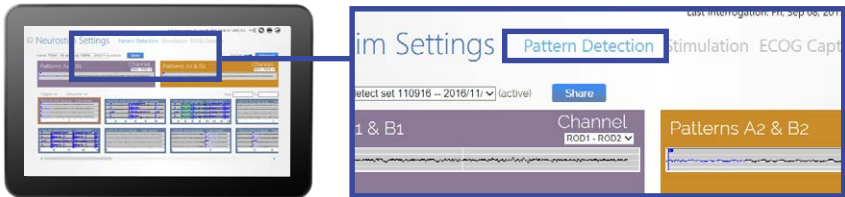
04. RNS CLINIC WORKFLOW

B. LOAD PATTERN DETECTION SET

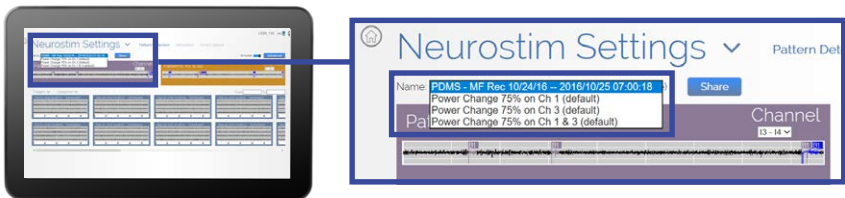
1. Go to “NeuroStim Settings” from the Home screen.



2. Select “Pattern Detection” from the center of the page.



3. Select “the desired set” from the droplist.

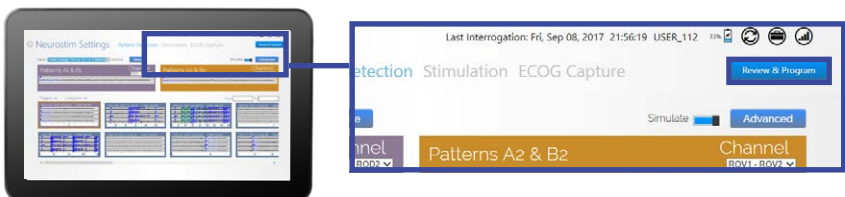


4. Detection set performance will be simulated in the ECoGs listed on the screen.

5. Review ECoGs of electrographic seizures to ensure ictal onsets are promptly detected.

6. Review scheduled ECoGs to ensure that normal baseline activity is not detected.

7. Select “Review & Program” button in top right corner.



05



BILLING OVERVIEW

Programming Coding and Billing Documentation

1. In order to bill for programming, you will need to document:
 - a. Work performed, including:
 - how many parameters were changed.
 - which parameters were changed.
 - what the changes were.

(See example from PDMS below)
 - b. Time spent (in minutes).
 - c. Provider that performed the work (MD vs. non-MD practitioner).

2. How to retrieve programming changes from PDMS:
 - a. On personal computer, navigate to PDMS and find patient of interest.
 - b. Click on the “Activity” Tile from the Home Screen.
 - c. Click on “Event List”.
 - d. Click on the most recent “Programming” from the Report List.
 - e. Parameters that have changed in the Detection and Stimulation sections will appear in a unique color – this report may be exported or screenshots may be taken for substantiation.

3. Example of Detection Settings from Programming Report:

Pattern A, First Detector (Not Inverted)

Bandpass (Technical Mode)							
Minimum Frequency Window	Minimum Frequency Count Criterion	Minimum Amplitude Bandpass Hysteresis	Minimum Amplitude	Maximum Frequency Minimum Width	Detect Analysis Window	Bandpass Threshold	Detection Persistence
160 ms	10	32	40	0 ms	768 ms	3	1 secs

Bandpass (Clinical Mode)			
Minimum Frequency	Maximum Frequency	Minimum Amplitude	Minimum Duration
28.85 Hz Sinusoid	125.00 Hz Sinusoid	3.91 %	0.384 secs



05. BILLING OVERVIEW

4. Example of Stimulation Settings from Programming Report:

	Therapy #1		Therapy #2		Therapy #3		Therapy #4	
	Pattern A Therapy	Pattern B Therapy	Burst #1	Burst #2	Burst #1	Burst #2	Burst #1	Burst #2
ROD1	+	-	+	-	+	-	+	-
ROD2	+	-	+	-	+	-	+	-
ROD3	+	-	+	-	+	-	+	-
ROD4	+	-	+	-	+	-	+	-
ROV1	-	+	-	+	-	+	-	+
ROV2	-	+	-	+	-	+	-	+
ROV3	-	+	-	+	-	+	-	+
ROV4	-	+	-	+	-	+	-	+
Can	0	0	0	0	0	0	0	0
Current	2.0 mA	5.0 mA	2.0 mA	5.0 mA	2.0 mA	5.0 mA	2.0 mA	5.0 mA
Frequency	200.0 Hz	200.0 Hz	200.0 Hz	200.0 Hz	200.0 Hz	200.0 Hz	200.0 Hz	200.0 Hz
PW Per Phase	160 µs	160 µs	160 µs	160 µs	160 µs	160 µs	160 µs	160 µs
Burst Duration	200 ms	200 ms	200 ms	200 ms	200 ms	200 ms	200 ms	200 ms
Estimated Charge Density	1.0 µC/cm ²	2.5 µC/cm ²	1.0 µC/cm ²	2.5 µC/cm ²	1.0 µC/cm ²	2.5 µC/cm ²	1.0 µC/cm ²	2.5 µC/cm ²

Commonly Used CPT Codes and Short Descriptors

CPT CODE	SHORT DESCRIPTOR
95970	→ Electronic analysis of implanted neurostimulator pulse generator system, without programming.
95971	→ Electronic analysis of implanted neurostimulator pulse generator system, with simple intraoperative or subsequent reprogramming.
95978	→ Electronic analysis of implanted neurostimulator pulse generator system with complex deep brain stimulator, initial or subsequent reprogramming; first hour.
95979	→ Each additional 30 minutes.



Coding/Billing Notes and Disclaimers

Analysis and programming may be furnished by a provider, with or without support from a manufacturer's representative. Neither the payer nor the patient should be billed for services rendered by the manufacturer representative. Contact your local Medicare contractor or other payer for interpretation of applicable policies.

According to CPT guidelines, complex programming is defined as changes to four or more parameters. The parameters include: rate, pulse amplitude, pulse duration, pulse frequency, eight or more electrode contacts, cycling, stimulation train duration, train spacing, number of programs, number of channels, alternating electrode polarities, dose time, or more than one clinical feature. In addition, CPT guidelines instruct providers to append modifier -52 to code 95978 if complex programming lasts less than 31 minutes.

An evaluation and management code may be reported if a separately identifiable evaluation and management service takes place in addition to analysis and programming.

This document is intended for informational purposes only. NeuroPace does not promise or guarantee coverage or any level of payment by any third party payer. While NeuroPace believes this information to be correct, it is subject to change at any time. As with all reimbursement claims, providers are solely responsible for determining the appropriate codes, modifiers and charges for services provided. NeuroPace recommends that you contact your local payer with questions regarding coding and payment guidelines.

06



VIDEO TUTORIALS

1. How to filter and view ECoGs



 **LINK TO YOUTUBE**
www.neuropace.com/ViewECoG

2. How to review patient trends



 **LINK TO YOUTUBE**
www.neuropace.com/ReviewTrends

3. How to review past programming settings



 **LINK TO YOUTUBE**
www.neuropace.com/ReviewProgramming


4. How to test and configure simulation



 **LINK TO YOUTUBE**
www.neuropace.com/ConfigureStim

5. How to load a pre-created detection set



 **LINK TO YOUTUBE**
www.neuropace.com/LoadDetection



APPENDIX

Commonly used ECoG triggers to initiate ECoG capture

Long Episode: when a detected episode exceeds the duration selected as the long episode length. Duration options range from 1 to 120 seconds.

Magnet: when the patient swipes the magnet over the Neurostimulator.

Saturation: when the ECoG amplitude becomes very high and saturates the amplifiers.

Scheduled: Scheduled time of day (up to four specific start times) for ECoG storage to capture baseline.

Brief Statement

NeuroPace® RNS® System Brief Disclosure

Indication for Use

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

Contraindications

The RNS® System is contraindicated for patients at high risk for surgical complications, with medical devices implanted that deliver electrical energy to the brain, and those who are unable (or do not have the necessary assistance) to properly operate the NeuroPace® Remote Monitor or Magnet. For patients with an implanted RNS® System the following medical procedures are contraindicated:

- Magnetic Resonance Imaging (MRI) -- The RNS® System is MR Unsafe.
- Electroconvulsive Therapy (ECT).
- Transcranial Magnetic Stimulation (TMS).
- Diathermy procedures (any treatment that uses high-frequency electromagnetic radiation, electric currents or ultrasonic waves to produce heat in body tissues).

Warnings and Precautions

The RNS® System is not compatible with non-NeuroPace leads and/or pulse generators. Electrical shock may occur with incorrect use of the Programmer or Remote Monitor. Do Not Resterilize and Do Not Reuse the implantable products.

Clinical Use

The RNS® System should only be implanted at Comprehensive Epilepsy Centers 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 and neurosurgeons with adequate experience in the management of intractable epilepsy and in the localization of epileptic foci. They must complete a NeuroPace® RNS® System training program and 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. In some instances Neurologists who meet the experience and certification requirements but do not practice at Comprehensive Epilepsy Centers could be qualified by NeuroPace to provide post-implant programming.

Surgical

Implantation of the RNS® System and associated surgical procedure risks may cause, but are not limited to, infection, intracranial hemorrhage, tissue damage, temporary pain at the implant site, CSF leakage, seroma, and paralysis.

RNS® System and Therapy

The safety and effectiveness has not been studied in pregnant women. The effects of long-term brain stimulation are not completely known. Strong electromagnetic interferences (EMI) can result in serious patient injury or death, damaged brain tissue, loss or change in symptom control, reoperation, stimulation to turn on or off, a return of symptoms,

or a momentary increase in stimulation felt by the patient. In addition EMI, such as security screening devices and radio frequency identification, can result in delivering the programmed stimulation to the patient and appear as sensing artifacts on the ECoG recordings. The RNS® System could interact with implanted cardiac devices and result in inappropriate device response or device damage. Additional surgical procedures can result from battery malfunction, electrical short, open circuit, lead fracture, lead insulation failure, damage as a result of head trauma, or lead migration. Severe brain tissue damage can result from exposure to battery chemicals if the Neurostimulator is ruptured or pierced due to outside forces. The patient must collect data from the Neurostimulator once a day and send data to the PDMS once a week.

Medical Environment

Electrolysis on the head and neck should be avoided. Prior to the administration of Extracorporeal Shock Wave Lithotripsy or high radiation sources the administering physician should consult with the physician prescribing the RNS® System. Read the user manual to understand the steps to be taken before, during and after computerized tomography (CT) scans.

Potential Adverse Events

Serious adverse events occurring in $\geq 2.5\%$ of patients and those of particular relevance reported during the RNS® System clinical studies include EEG monitoring, infection, change in seizures, medical device removal, death, device lead damage or revision, antiepileptic drug toxicity, hemorrhage, psychiatric events, status epilepticus and seizure-related injury. Refer to the product labeling for a detailed disclosure of other reported adverse events.

R_XOnly

See important prescribing and safety information in the RNS® System labeling. This is intended as supplementary information and should be used in conjunction with the labeling. Refer to the labeling for a description of the RNS® System and its components, indications for use, contraindications, warnings, cautions, adverse events and instructions for use. The manuals are available at www.NeuroPace.com or call or call 866-726-3876 for a paper copy.

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