RNS® System Programming Manual

For the RNS® Patient Data Management System (PDMS) and the RNS® Tablet (Programmer)

℞ Only

DN 1033876 Rev. 4
Rev. Date: 2026-06-03

About this Manual

This manual includes instructions for use for:

- The NeuroPace® Patient Data Management System (PDMS) Application software
- The RNS Tablet (Programmer) with Application software

Note: *The RNS Tablet (Programmer) model 5000 is compatible with the RNS Neurostimulator model RNS-300M and model RNS-320.*

Note: *In this document, the term "programmer" refers to the RNS Tablet (Programmer), the term "neurostimulator" refers to the RNS Neurostimulator, and the term "wand" refers to the Wand.*

Note: *The term "clinician" refers to a healthcare professional (HCP) trained in the use of the RNS System.*

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

This manual includes information about the secure NeuroPace Patient Data Management System (PDMS) database, which is accessible using a web browser on a personal computer or the programmer (RNS Tablet). This manual also contains information about the RNS Programmer, which is used to program how the RNS Neurostimulator operates.

Refer to the RNS System manual for indications for use, contraindications, warnings, cautions and additional device descriptions, device specifications and instructions for use.

Refer to the clinical summary booklet for information on the clinical study results of the RNS System and adverse event data.

All NeuroPace manuals are available at *www.neuropace.com* or by contacting NeuroPace, Inc. (see *Contact NeuroPace* on back page).

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.

This format is used to identify figure titles and descriptions.

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.*

CONTENTS

PRODUCT DESCRIPTION OVERVIEW

RNS SYSTEM OVERVIEW

The RNS System automatically delivers responsive electrical stimulation to reduce the frequency of partial onset seizures. Note that the RNS System is not a seizure detection device. The RNS System comprises sterile, implantable, and non-sterile external products, as illustrated by the diagram below.

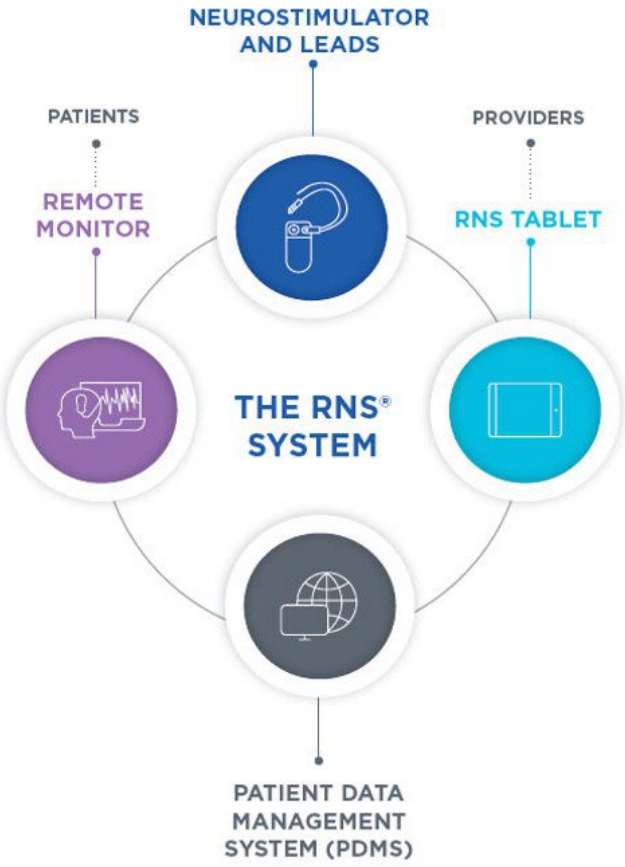


Figure 1 Elements of the RNS System

Specifically, this manual describes the following components of the RNS System and their functionality.

- NeuroPace Patient Data Management System (PDMS) Application software model 4340
- RNS Programmer model 5000 with application software and Wand model W-02

NEUROPACE PATIENT DATA MANAGEMENT SYSTEM

The Patient Data Management System (PDMS) is a secure online Application software that maintains patient and RNS Neurostimulator data obtained from the programmer (referred to as the RNS Programmer) and remote monitor. The PDMS is used to perform patient data review using the analytical Application software, and then create and share programming sets. Authorized users may access the PDMS via the Internet using a personal computer or via the programmer. An electronic signature in the form of a username and password are required for user authentication.

RNS PROGRAMMER

The RNS Programmer runs a proprietary NeuroPace application software and uses a custom telemetry component (Wand model W-02) to communicate with the RNS Neurostimulator by holding the wand over it. The wand is applied to the patient (an applied part). RNS Programmer is healthcare professional (HCP) facing, meaning that the HCP interacts with the product.

Clinicians can use the programmer to program how the neurostimulator operates. Settings include, but are not limited to, the implanted RNS Neurostimulator configuration, sensing and detection settings adapted to the patient's ECoG patterns, settings for ECoG record storage, and settings of the stimulation therapies.

Clinicians can also use the programmer to review previously retrieved neurostimulator activity information, perform detection analysis, and communicate with the PDMS via the Internet.

Note: *Programming is a Clinician supervised activity, and it is initiated only on a Programmer.*

PRODUCTS, INCLUDING ACCESSORIES AND MODEL NUMBERS

The PDMS Application software, model 4340 is available via the Internet using a personal computer or via the programmer. The RNS Programmer with Application software is provided as a kit, model 5001, which includes an AC Adapter and Carrying Bag.

Table 1 RNS System Products

Item	Model Number
NeuroPace Patient Data Management System (PDMS) Application software	4340
RNS Programmer Kit, model 5001	
RNS Programmer (with attached case)	5000
AC Adapter	
Carrying Bag	
Used With	
Wand	W-02

Note: *Manuals and other literature are not included in the list above. All NeuroPace manuals are available at www.neuropace.com or by contacting NeuroPace, Inc. (see* Contact NeuroPace on back page*).*

This manual contains information applicable to the RNS Programmer, which is used to program how the RNS Neurostimulator operates. It includes information about the secure NeuroPace Patient Data Management System (PDMS) database, which is accessible using the programmer or a web browser on a personal computer.

Refer to the RNS System manual for additional device descriptions, device specifications, and indications for use, contraindications, warnings, cautions, and instructions for use.

All NeuroPace manuals are available at *www.neuropace.com* or by contacting NeuroPace, Inc. (see *Contact NeuroPace* on back page).

Refer to the clinical summary booklet for information on the clinical study results of the RNS System and adverse event data.

WARNINGS AND CAUTIONS

WARNINGS

Note: See the RNS System manual for warnings and cautions regarding other components of the RNS System.

WARNING: The RNS® System should only be implanted by neurosurgeons with adequate experience in the implantation of subdural electrodes, the 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, that is, “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).

WARNING: MRI Safety Information

Note: MRI Mode software buttons and features are available only when you interrogate an RNS® Neurostimulator model RNS-320, which is MR Conditional.

RNS Neurostimulator model RNS-320: Refer to the MRI Guidelines for the RNS® System to determine patient eligibility for MRI and for the specific conditions required to safely perform an MRI scan on patients implanted with an RNS® Neurostimulator model RNS-320. 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 manuals are available at www.NeuroPace.com or by contacting NeuroPace, Inc.

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

RNS System External Components: All external components and accessories such as the Magnet, RNS Programmer (Programmer), NeuroPace 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: 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: 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 *124* 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 intracranial EEG activity to the neurostimulator. Signals that appear as intracranial EEG 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 intracranial EEG 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 *124* for more information.

WARNING: NeuroPace Components

Use of accessories, transducers, and cables other than those provided by NeuroPace could result in increased electromagnetic emissions or decreased electromagnetic immunity of the RNS System and result in improper operation. 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 System, including cables. Otherwise, degradation of the performance of the RNS System could result.

WARNING: NeuroPace Equipment Placement

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

CAUTIONS

Caution: Electromagnetic Interference (EMI)

Communications between the programmer and the implanted RNS neurostimulator may be interrupted by emissions from nearby electronic devices. Examples of sources of EMI are lithotripsy, computer monitors, cellular telephones, motorized wheelchairs, 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 *112* for more information.

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 clinician should be aware of possible sensing artifacts when assessing the ECoG recordings.

Caution: After Discharge Activity

If evidence of after discharge 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: 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: 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: Placement of the Programmer Power Cord

When charging the RNS Programmer, take care to ensure nothing rests on the programmer power cord and that the power cord is not located where charging could be interrupted.

Caution: Heating

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

TYPICAL CLINICAL WORKFLOWS

OVERVIEW

The PDMS is a secure, online patient and product data platform that is used to support ongoing clinical care. The RNS Programmer is used to program neurostimulator settings. Each is used in clinical workflows as described below.

SURGICAL WORKFLOW

During the initial implantation of the RNS Neurostimulator, live ECoGs are reviewed using the programmer, and initial default ECoG capture and detection settings are selected and programmed.

PDMS WORKFLOW

Ongoing clinical care, when patient data review occurs, is usually and preferably performed on the PDMS before a patient clinical visit, but can happen during a patient clinic visit. Patient data review occurs on the PDMS. Data review encompasses patient and neurostimulator information, ECoG review, review of activity charts, review of trends of ECoGs of Interest, and creating, reviewing, saving and sharing programming sets. See *Typical PDMS Workflow* on page *18*.

PROGRAMMER WORKFLOW

Ongoing clinical care, when programming is implemented, is during an interactive interrogation session with the RNS Programmer during a patient visit. Programming can include changing settings for ECoG capture, detection and responsive therapy. Programming sets are created on the PDMS and shared to the programmer for RNS Neurostimulator programming after interrogation. See *Typical RNS Programmer Workflow* on page *79*.

The components of ongoing clinical care are summarized in the following figure.

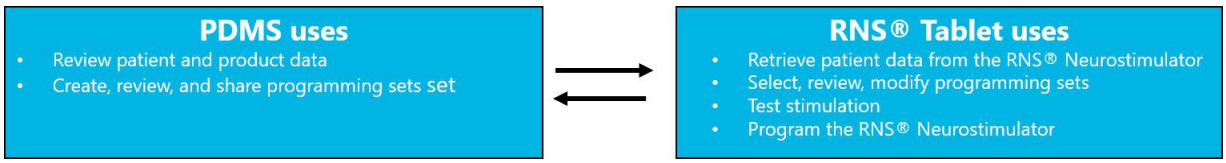


Figure 2 Components of ongoing clinical care

USING THE PDMS

PDMS ACCESS

This section of the manual provides instructions on how to use the PDMS Application software from a browser.

> ***Note:*** *The PDMS Application software can also be accessed via the programmer. Access using the programmer is described in* *Log In to the PDMS on the RNS Programmer on page 75**.*

The section provides instruction on logging in, accessing patient lists and patient data from each functional area of PDMS, and recommended patient follow-up activities.

PDMS LOG IN

Access to the secure PDMS database from a browser requires a username and password. If NeuroPace has not already provided these to you, contact NeuroPace to obtain a username and temporary password (see *Contact NeuroPace* on back page). After logging in for the first time using the temporary password provided by NeuroPace, you will be prompted to change your password. You are responsible for maintaining the confidentiality of your username and password.

1. Using any computer with Internet access, open a web browser and select the PDMS link on www.neuropace.com
2. On the NeuroPace home page select the PDMS link.
3. Enter your Username and Password.
4. Click **LOG IN**.

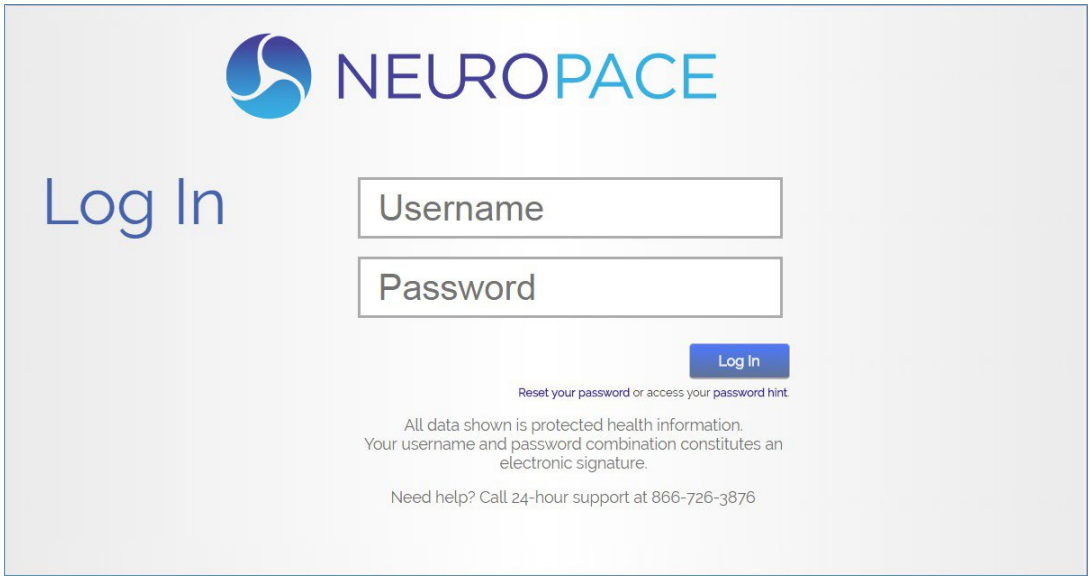


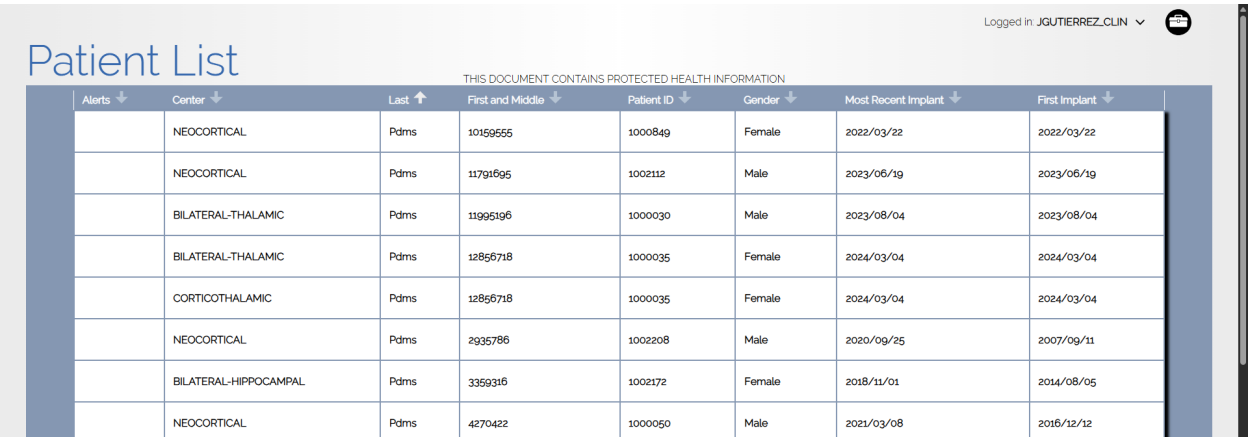
Figure 3 PDMS Login on a personal computer

PASSWORD RESET

If you have forgotten your password, select **RESET YOUR PASSWORD OR ACCESS YOUR PASSWORD HINT**. The password hint you entered will be sent to the email address listed in your PDMS profile.

THE PATIENT LIST

The **PATIENT LIST** opens after logging in. Scroll to find and select the desired patient data.



Alerts	Center	Last	First and Middle	Patient ID	Gender	Most Recent Implant	First Implant
	NEOCORTICAL	Pdms	10159555	1000849	Female	2022/03/22	2022/03/22
	NEOCORTICAL	Pdms	11791695	1002112	Male	2023/06/19	2023/06/19
	BILATERAL-THALAMIC	Pdms	11995196	1000030	Male	2023/08/04	2023/08/04
	BILATERAL-THALAMIC	Pdms	12856718	1000035	Female	2024/03/04	2024/03/04
	CORTICOTHALAMIC	Pdms	12856718	1000035	Female	2024/03/04	2024/03/04
	NEOCORTICAL	Pdms	2935786	1002208	Male	2020/09/25	2007/09/11
	BILATERAL-HIPPOCAMPAL	Pdms	3359316	1002172	Female	2018/11/01	2014/08/05
	NEOCORTICAL	Pdms	4270422	1000050	Male	2021/03/08	2016/12/12

Figure 4 Patient List Screen

PDMS HOME SCREEN OVERVIEW

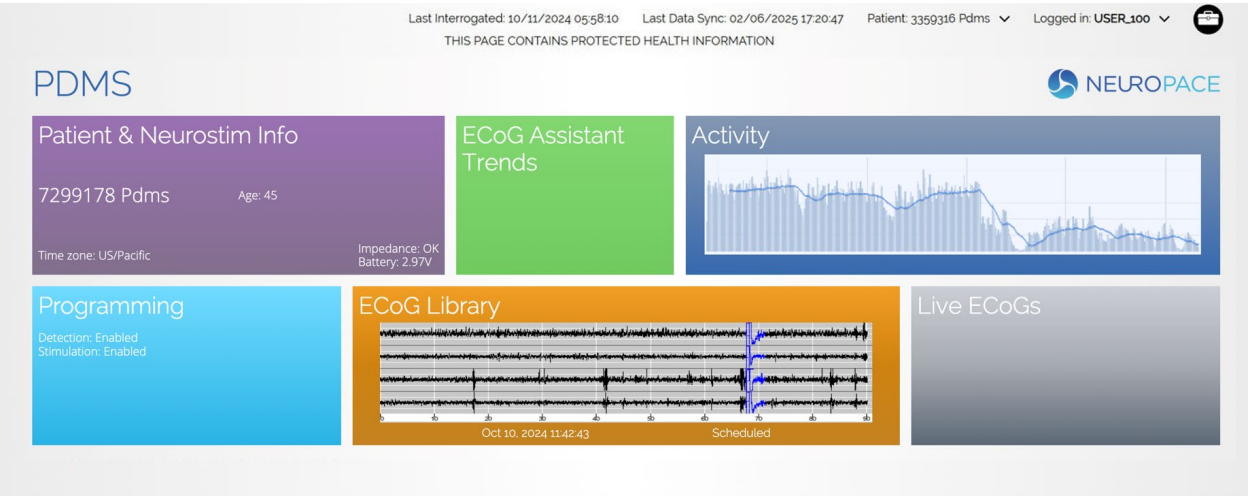


Figure 5 PDMS Home Screen

The **PDMS HOME SCREEN** opens when a patient record is selected on the **PATIENT LIST**. This is the hub for all activities related to monitoring a patient and planning changes to their treatment.

The **PDMS HOME SCREEN** has six colored tiles, each providing different types of data and functionality when selected.

PATIENT & NEUROSTIM INFO

Select the purple **PATIENT & NEUROSTIM INFO** tile to check basic information about the patient and RNS Neurostimulator status and programmed parameters. For details, see *Review Patient & Neurostim Info* on page *18*.

REVIEW ECOG ASSISTANT TRENDS

Select the green **ECoG Assistant Trends** tile to access the **ECoG Assistant Trends Report**. This report provides an analytical summary of a patient's ECoGs of Interest over a selected time frame.

The report is available only by accessing the PDMS from a browser; it is not available on the RNS Programmer. For details, see *Review ECoG Assistant Trends* on page *24*.

ACTIVITY

Select the dark blue **ACTIVITY** tile to open the **ACTIVITY** screen. The **ACTIVITY** screen enables review of the ECoG capture, and detection and stimulation settings used over time. For details, see *Review Activity* on page *28*.

PROGRAMMING

Select the light blue **PROGRAMMING** tile to access the **PROGRAMMING** screen. Programming sets, which can include changes to ECoG capture settings, changes to detection settings, and changes to stimulation settings, are created and shared via the **PDMS PROGRAMMING** screen. For details, see *Create a Programming Set* on page *35* and *Share a Programming Set* on page *36*.

ECOG LIBRARY

Select the orange **ECoG LIBRARY** tile to open the **ECoG LIBRARY**. The **ECoG LIBRARY** displays thumbnails of all ECoGs stored for the current patient. An important feature of the **ECoG LIBRARY** is the **ECoG Assistant** functionality. For details, see *Review ECoG Library* on page *20* and *ECoG Assistant Functionality* on page *22*.

LIVE ECOGS

Access to the grey **LIVE ECOGS** tile functionality is not available on the PDMS.

PDMS PROFILE AND SETTINGS

The toolbox icon at upper right of every screen gives access to view and change your:

- Profile - including your email address to be used for logging in and for password reset
- Password
- Time Zone

TYPICAL PDMS WORKFLOW

OVERVIEW

The following activities are recommended in preparation for a follow-up visit:

- Log in to PDMS and access a patient record. See *PDMS Access* on page *15*.
- Review patient information and neurostimulator status, paying particular attention to any alerts. See *Review Patient & Neurostim Info* on page *18* and *Alerts* on page *104*.
- Review ECoG records using ECoG Assistant features. See *Review ECoG Library* on page *20* and *ECoG Assistant Functionality* on page *22*.
- Review summary report of ECoG Assistant trends. See *Review ECoG Assistant Trends* on page *24*.
- Review neurostimulator activity, including programming epochs and events such as magnet swipes, interrogations, and detections. See *Review Activity* on page *28*.
- Plan for programming changes to ECoG capture, detection and stimulation settings. Carefully review all pending changes before saving them as a programming set. See *Create a Programming Set* on page *35*.
- Share the new programming set to make it available on the RNS Programmer used for programming the neurostimulator. See *Share a Programming Set* on page *36*.

REVIEW PATIENT & NEUROSTIM INFO

On the **PDMS HOME** screen, select the purple **PATIENT & NEUROSTIM INFO** tile.

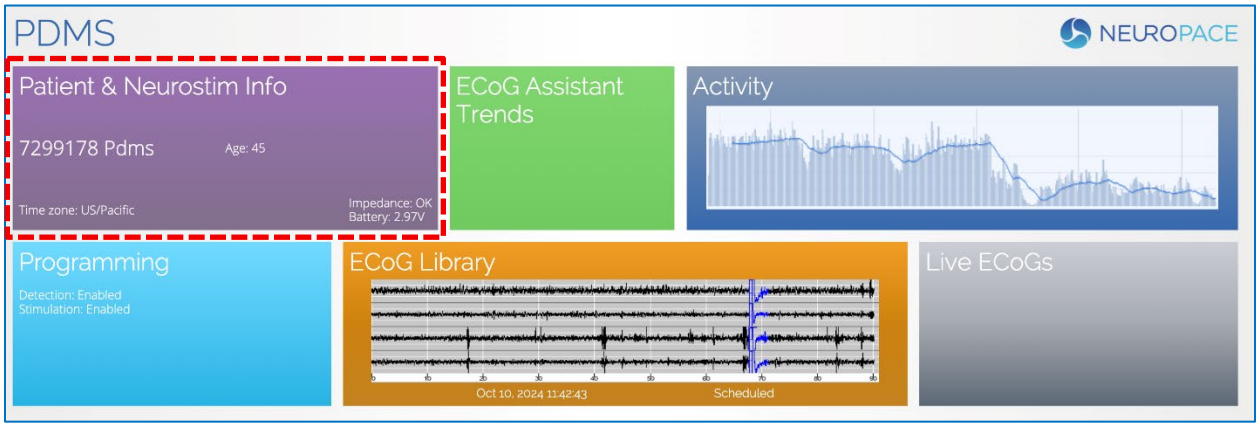


Figure 6 Select Patient & Neurostim Info tile on Home screen

Basic information about the patient and RNS Neurostimulator status are reported. Additionally, alerts about the device status are reported. It is important to review any alerts. For detailed information on alerts, see *Alerts* on page *104*.

Figure 7 Patient and Neurostim Info Screen

This screen provides:

- At upper left, patient information. Select **CURRENTLY IMPLANTED PRODUCT** to see details about the implanted products.
- At middle left, whether Detection and Stimulation are Enabled or Disabled.
- At upper center, information about the neurostimulator (serial number, implant date), leads, and electrodes.
- At lower center (swipe up or scroll to see), graphs of battery and impedance measurements over time.

REVIEW ECOG LIBRARY

Select the orange **ECOG LIBRARY** tile. This opens the **ECOG LIBRARY**. The **ECOG LIBRARY** displays thumbnails of all ECoGs stored for the current patient.

It is recommended to review ECoGs stored in the library to assess how early and how often detections occur and the electrographic response to stimulation therapies that have been delivered.

An important feature accessed through the **ECOG LIBRARY** is *ECoG Assistant Functionality* on page *22*.

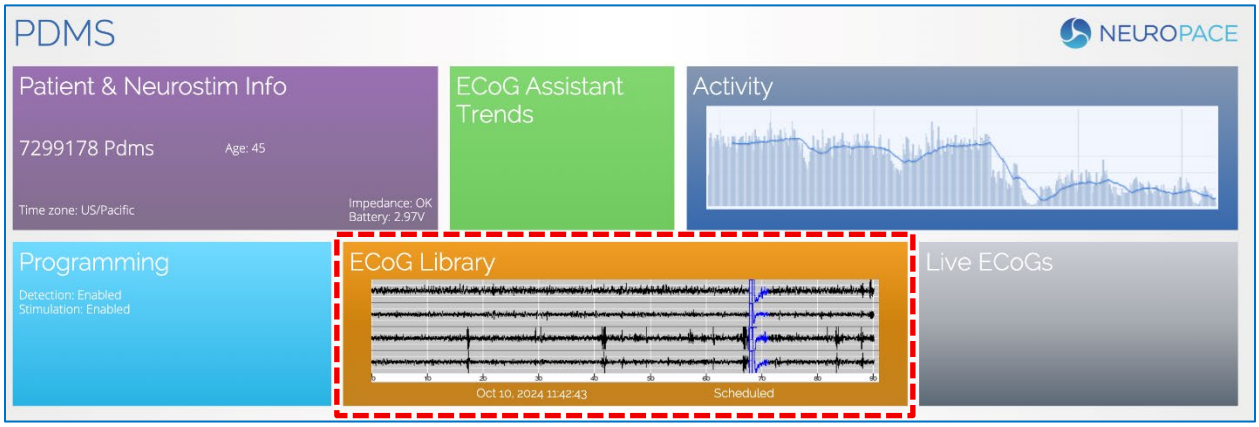


Figure 8 Select ECoG Library tile on Home screen

Ensure ictal onsets are promptly detected. Review scheduled ECoGs to ensure normal baseline activity is not detected.

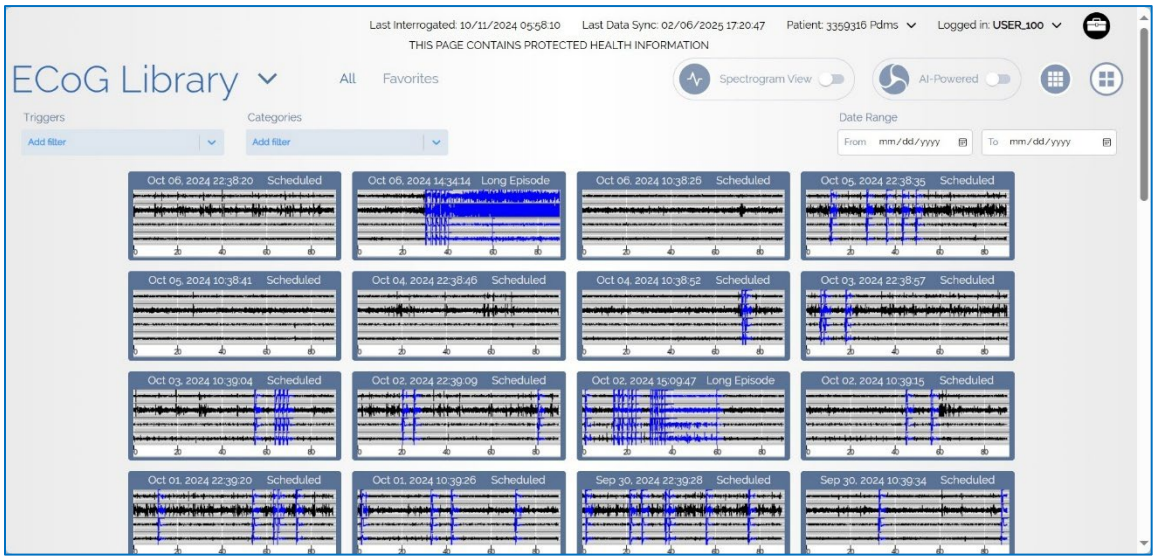


Figure 9 ECoG Library screen

Each ECoG is identified by date and time captured and by capture trigger. Newest ECoGs are on top, older ones toward the bottom. Scroll up or down to view all ECoGs. You can filter which ECoGs are displayed using **TRIGGERS** and **CATEGORIES** at upper left. Use the **FROM** and **TO** fields at upper right to view ECoGs by date range.

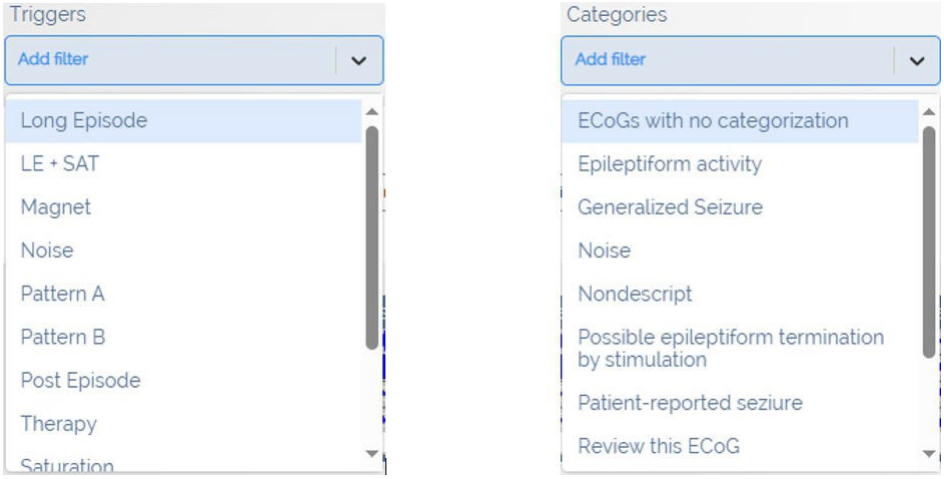


Figure 10 Filter stored ECoGs by triggers and categories

At top center, you can select **ALL** or **FAVORITES** to display ECoGs by those classifications. Select a thumbnail to open it in a larger size, as shown below.

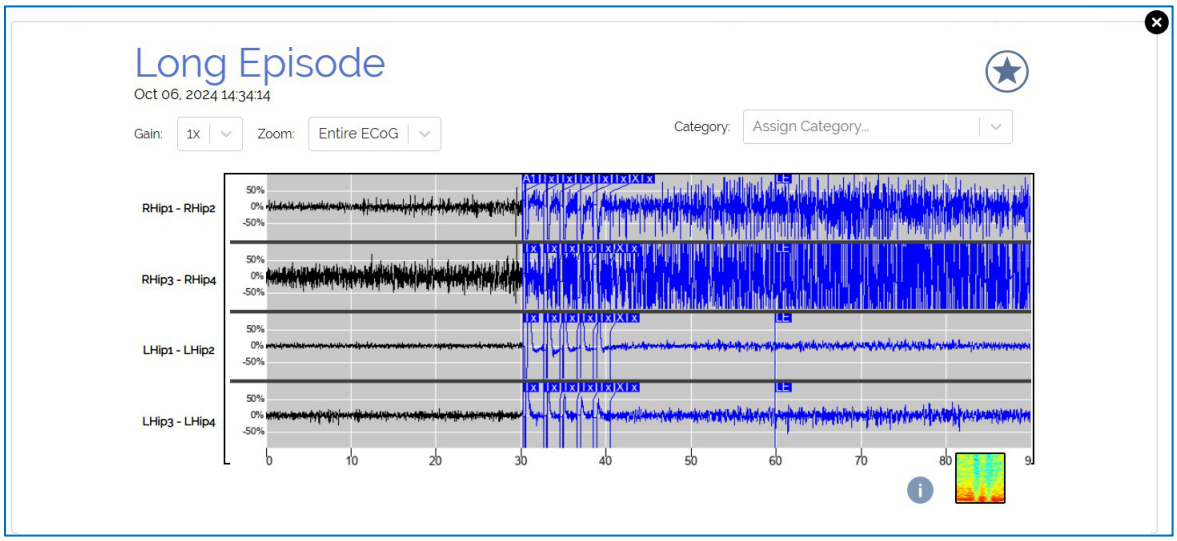


Figure 11 Viewing a Single ECoG

ECoGs highlight detection and stimulation events. Detected activity appears in blue. Undetected activity appears in black. Colored flags mark specific points of detection (A1, B1, etc.) or stimulation (Tr). You can **ZOOM** in on the ECoG and increase the **GAIN**. Use the **ASSIGN CATEGORY** field to assign the ECoG to a category. Select the **STAR** button at upper right to specify this ECoG as a favorite, for fast access later using the **FAVORITES** filter on the **ECOG LIBRARY** screen.

Captured ECoGs reside in the RNS Neurostimulator memory until they are transferred to the programmer at the next interrogation with the wand, and are then cleared from memory. If neurostimulator memory capacity is reached, captured ECoGs are overwritten by subsequent ECoGs. The number of ECoGs that can be stored depends on the duration of each ECoG, which you can specify in the **CAPTURE WINDOW** field in the **DURATION** area on the far upper right side of the **ECOG CAPTURE** screen. See *Configure ECoG Capture* on page *48* for details.

ECOG ASSISTANT FUNCTIONALITY

From the **PDMS HOME** screen, select the orange **ECOG LIBRARY** tile. This opens the ECoG Library.

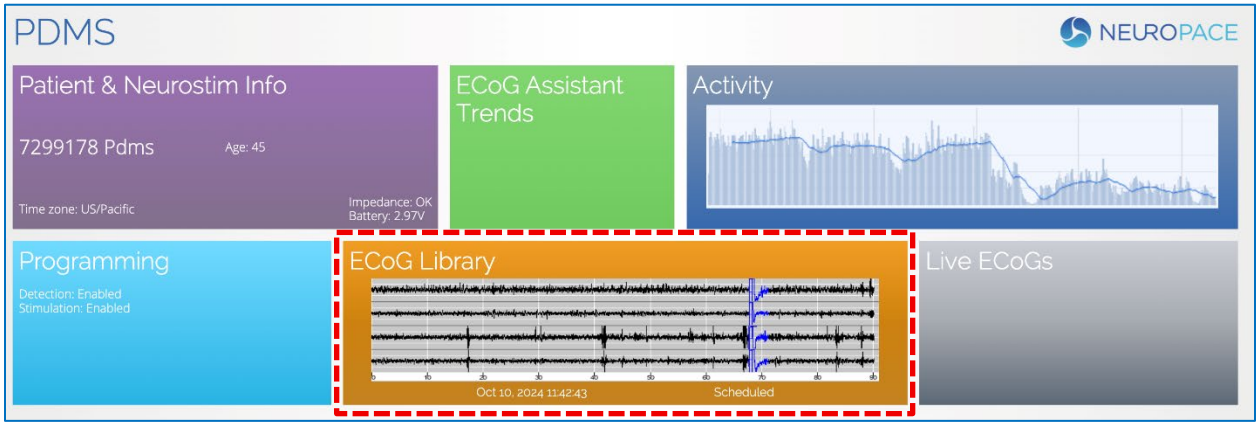


Figure 12 Select ECoG Library tile on Home screen

To access the **AI-POWERED ECOG ASSISTANT** functionality, select the **AI-POWERED** toggle at upper right to turn it on. By default, if no date range is specified, the library will display one year of ECoGs since the most recent data upload. Select the desired date range to see more or less ECoGs. Scroll down if necessary to see more ECoGs.

Figure 13 Using ECoG Assistant in the ECoG Library

Note the disclaimer text near top center on all AI-powered screens: ECoG Assistant is a tool for identifying ECoGs of Interest and does not replace clinical review and judgment. ECoG Assistant was developed on long episode, magnet, and saturation ECoGs, and excludes scheduled and user-saved ECoGs. For clinical supporting data, see *Appendix A: Data Supporting the ECoG Assistant AI Algorithm* on page *133*.

Use the **FROM** and **TO DATE RANGE** fields at upper right to define a date range. Generate the report by selecting the large blue button at upper right **ECoG Assistant Trends Report**.

> ***Note:*** *Only the date range filters apply to this report, and only if they are active. You can access the report without selecting a date range. The maximum date range is 24 months.*

Besides date, there are two **ECoG Assistant Categorization** options above the ECoGs to the left. Each one shows the count of that type of ECoG in parentheses. You can use the following options.

- **ECOGS OF INTEREST** (count in parentheses): ECoGs classified as ECoGs of Interest.
- **NOT ECOGS OF INTEREST** (count in parentheses): ECoGs which were not classified as ECoGs of Interest.

The **TRIGGERS** and **CATEGORIES** filters remain available for use at upper left, as do **ALL** and **FAVORITES**. These filters are combined with all others selected. This means the resulting display of ECoGs and the counts reflect application of all filters applied at once.

Note that you have the option to display ECoGs in **SPECTROGRAM VIEW** using the toggle at upper right-center next to **AI-POWERED**. You can also toggle off **AI-POWERED** to remove filtering for ECoGs identified as ECoGs of Interest.

Figure 14 Spectrogram View using ECoG Assistant

REVIEW ECOG ASSISTANT TRENDS

Select the green **ECoG Assistant TRENDS** tile. This opens the **ECoG Assistant TRENDS REPORT** which provides an analytical summary report of a patient's ECoGs of Interest over a selected time frame.

> ***Note:*** *This functionality is available only by accessing PDMS using a personal computer; it is not available through the RNS Programmer.*

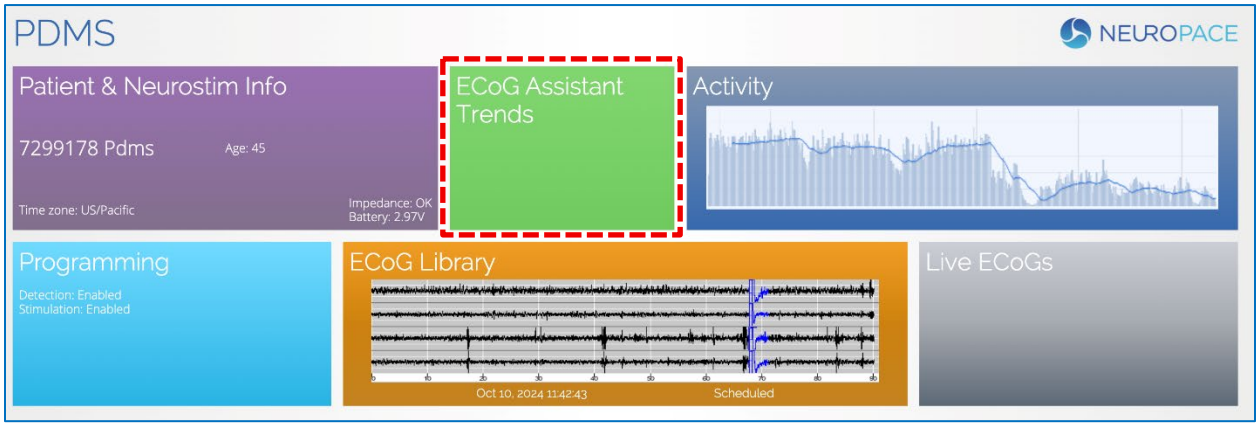


Figure 15 Select ECoG Assistant Trends tile on Home screen

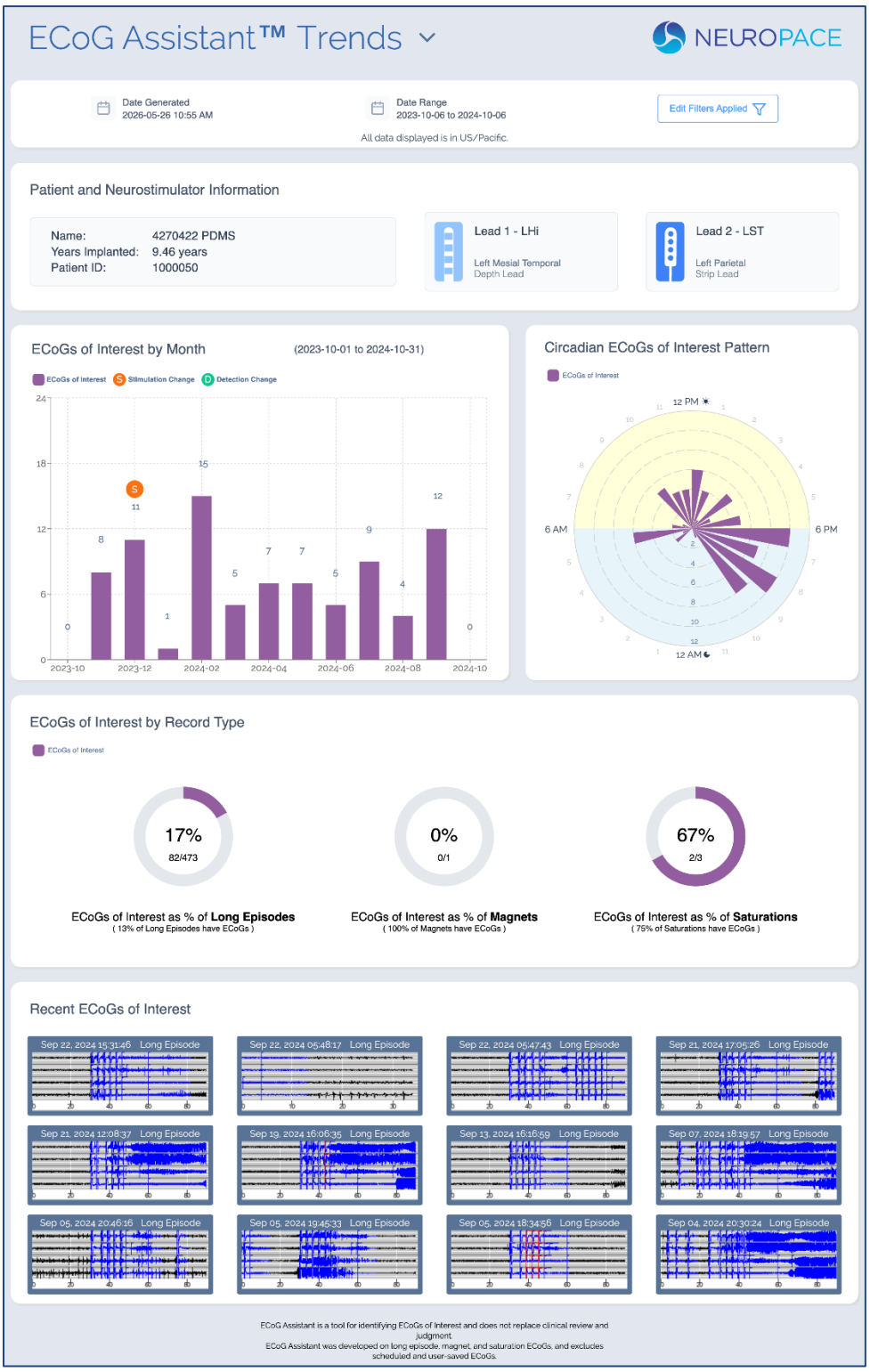


Figure 16 ECoG Assistant Trends Report

- The top of the page shows the **DATE GENERATED** and the **DATE RANGE** of the report. The default date range is 12 months, the minimum is 30 days, and the maximum is 24 months.
- Select **EDIT FILTERS APPLIED** at upper right to go to the ECoG Library where you can change the date range and then regenerate the report. All elements of the report show information for a maximum of 24 months.

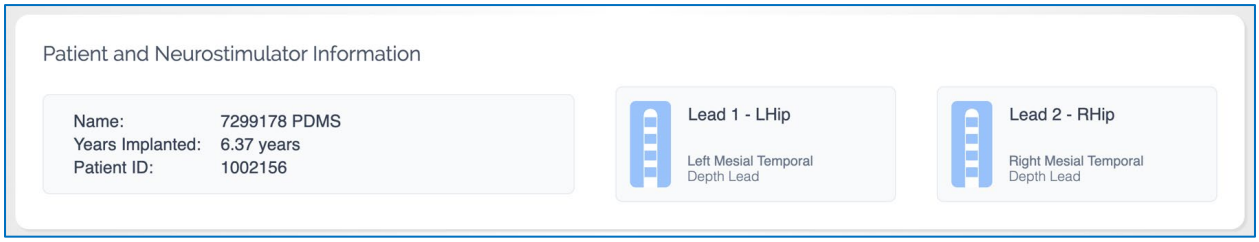


Figure 17 Top part of report

- **PATIENT AND NEUROSTIMULATOR INFORMATION**: The upper portion of the report shows information about the patient (including name and patient ID), the years implanted, and the type of leads implanted.
- **Leads Information:** Information about the implanted leads is provided at upper right.

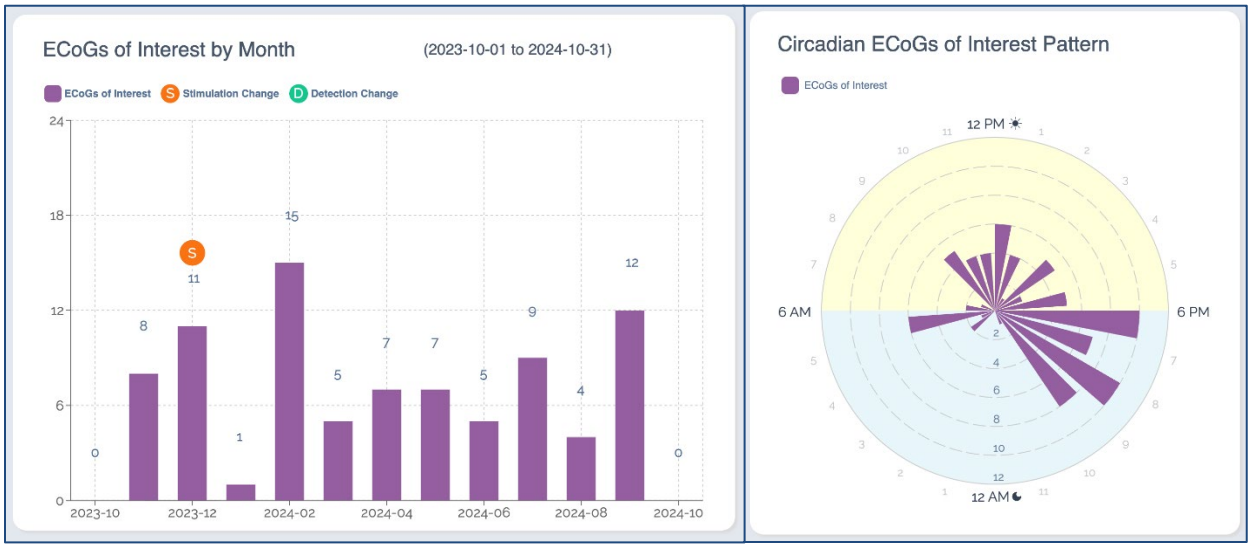


Figure 18 Time-based report of ECoGs of Interest

- **ECOGS OF INTEREST BY MONTH AND CIRCADIAN ECOGS OF INTEREST PATTERN:** The middle portion of the report shows two time-based visualizations of patterns of capture of ECoGs of Interest – monthly patterns over the selected date range and circadian patterns showing time-of-day-distribution. All aspects of the report can, like this month-by-month graph, show information for a maximum of 24 months. The circadian pattern is based on the date range.
- The monthly graph of ECoGs of Interest shows an orange S dot to indicate a change in stimulation settings applied, and a green D dot to indicate a change in detection settings applied.
- The circadian pattern shows when ECoGs of Interest were captured during the day.

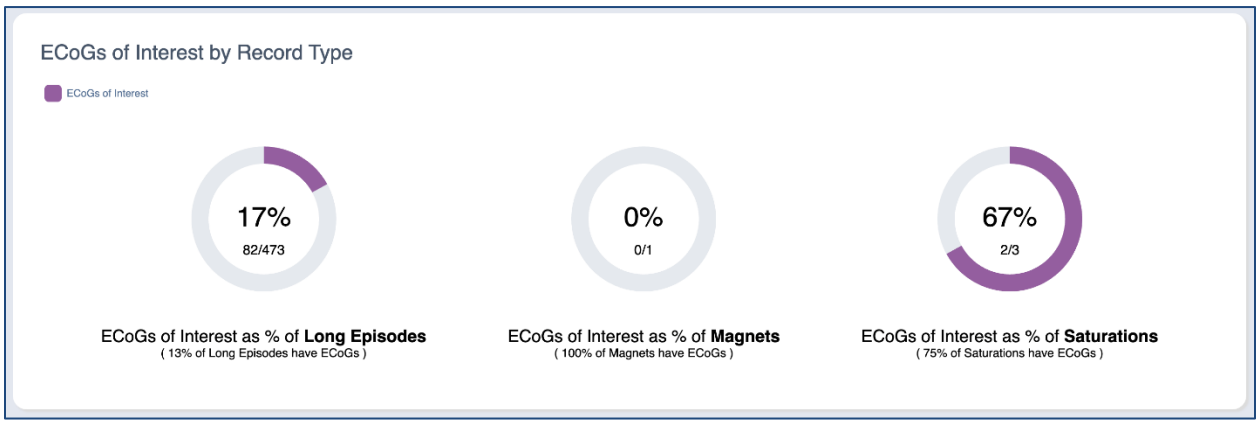


Figure 19 ECoGs of Interest by Record Type

ECoGs of Interest by Record Type: The bottom portion of the report reflects the proportion of some common ECoG capture triggers that result in capture of ECoGs of Interest.

The common triggers reported above are for, specifically, from left to right:

- Long episode ECoGs
- Magnet ECoGs
- Saturation ECoGs

The panel **ECoGs of Interest by Record Type** provides insights into classification for Long Episode, Magnet, and Saturation ECoG storage triggers. Specifically, it indicates the following:

- The percentage and count of ECoGs classified as ECoGs of Interest seizures out of the total available for review (displayed within the circle plot).
- The completeness of storage for each trigger type (shown below the circle plot).

For example, the figure above indicates that 17% (82/473) of Long Episode triggered ECoGs were classified as ECoGs of Interest. Additionally, the smaller text beneath the circle plot shows that 13% of Long Episode events were stored and analyzed, while the remaining 87% were overwritten and not available for review or analysis.

If only a small portion of a specific trigger type has ECOGs available for analysis, the user should apply clinical judgment when interpreting the data, considering its limited completeness.

At the bottom of the report there are samples of **RECENT ECOGS OF INTEREST**.

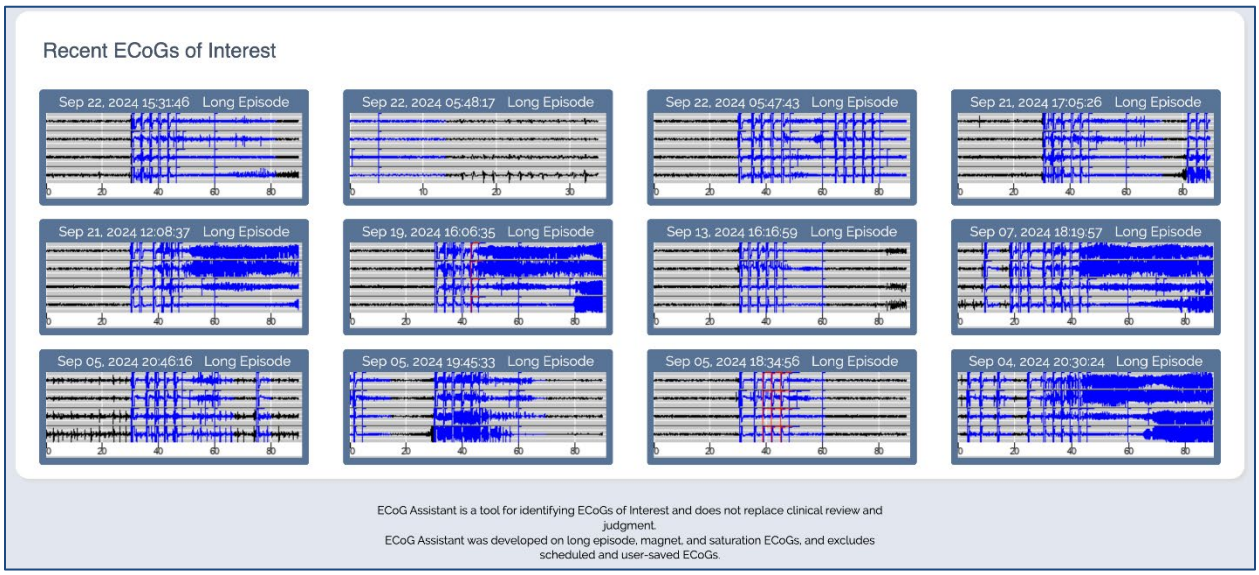


Figure 20 Recent ECoGs of Interest

Note the disclaimer text at bottom center: ECoG Assistant is a tool for identifying ECoGs of Interest and does not replace clinical review and judgment. ECoG Assistant was developed on long episode, magnet, and saturation ECoGs, and excludes scheduled and user-saved ECoGs. For clinical supporting data, see *Appendix A: Data Supporting the ECoG Assistant AI Algorithm* on page *133.*

REVIEW ACTIVITY

Select the dark blue **ACTIVITY** tile to open the **ACTIVITY** screen.

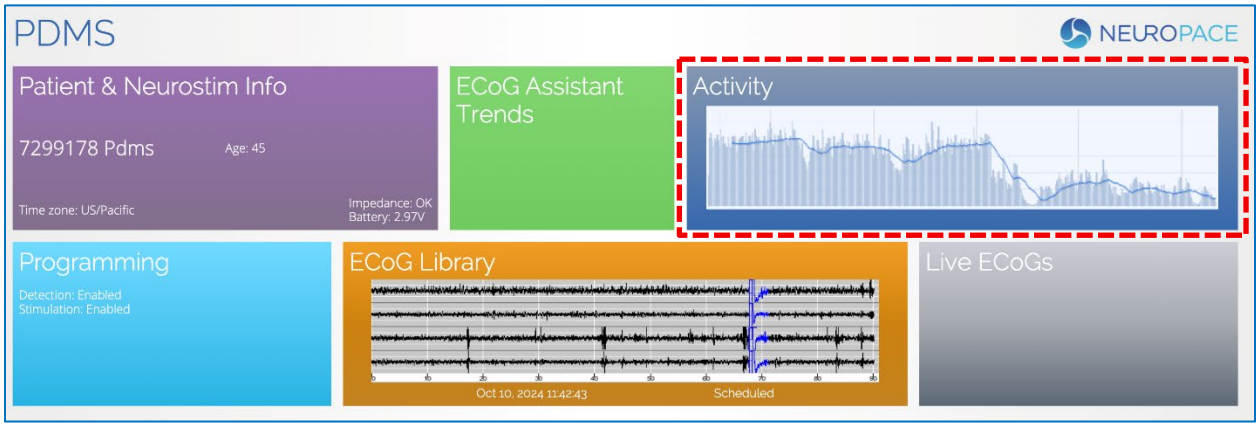


Figure 21 Select Activity tile on Home screen

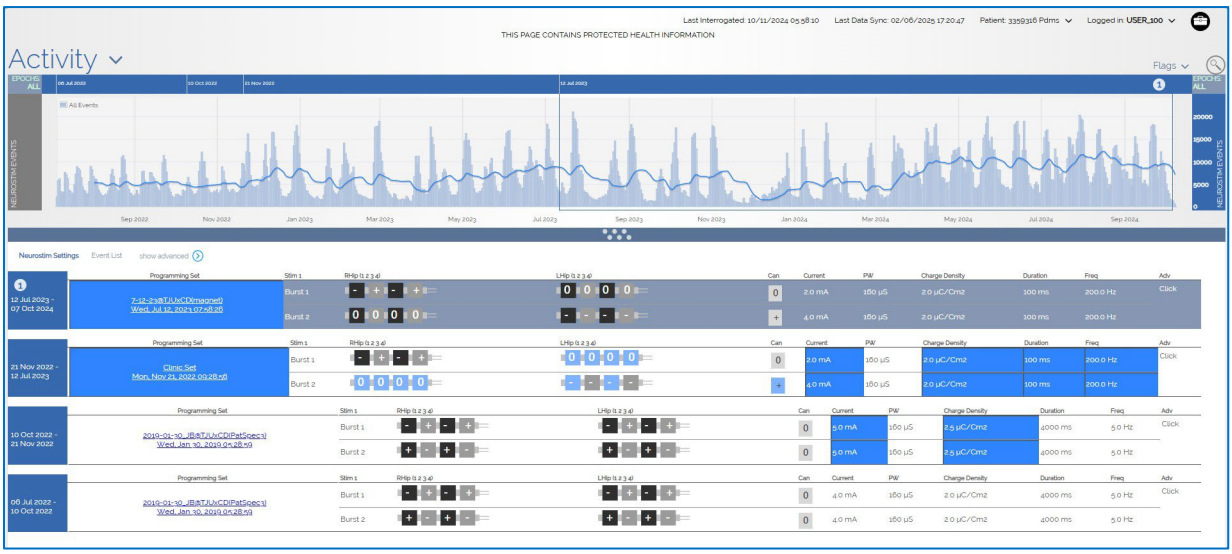


Figure 22 Activity screen

The upper segment of the **ACTIVITY** screen is a histogram that shows the number of detection and stimulation events over time. Scroll left or right over the dates to view earlier or later activity.

The lower segment of the screen shows (by default) a list of the **NEUROSTIM SETTINGS** - detection and stimulation settings - used over time, one row for each period of time between programming changes, which is called a programming epoch. More view options are described below.

ACTIVITY HISTOGRAM VIEWING OPTIONS

The interface provides many options for viewing activity.

- Select **EPOCHS** at upper left or right to see events from **ALL EPOCHS**, **DETECTION ONLY** or **STIMULATION ONLY**.

Figure 23 Select Epoch type

- Select **FLAGS** at upper right to see events flagged with **MAGNET SWIPE**, **OFFICE INTERROGATION** or **IMPLANTS**.

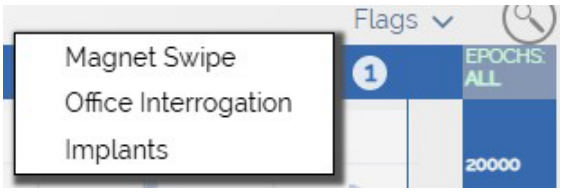


Figure 24 Select Flags type

- Select **NEUROSTIM EVENTS** on the left or right sides of the histogram to select items for layering on the graph; you can select multiple items concurrently, up to all items in the upper part of the list.

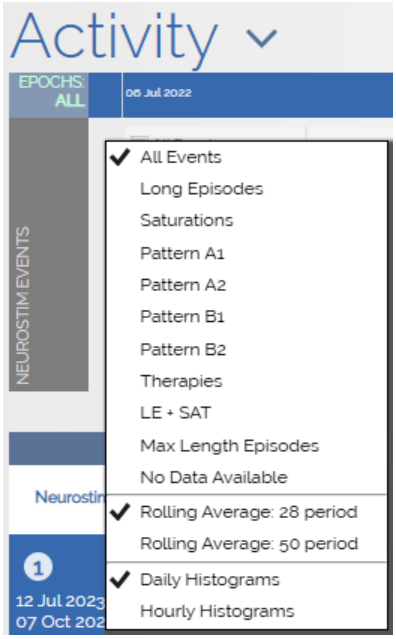


Figure 25 Select Activity Types to Display

A color legend appears on the left to help you recognize what is on the histogram.

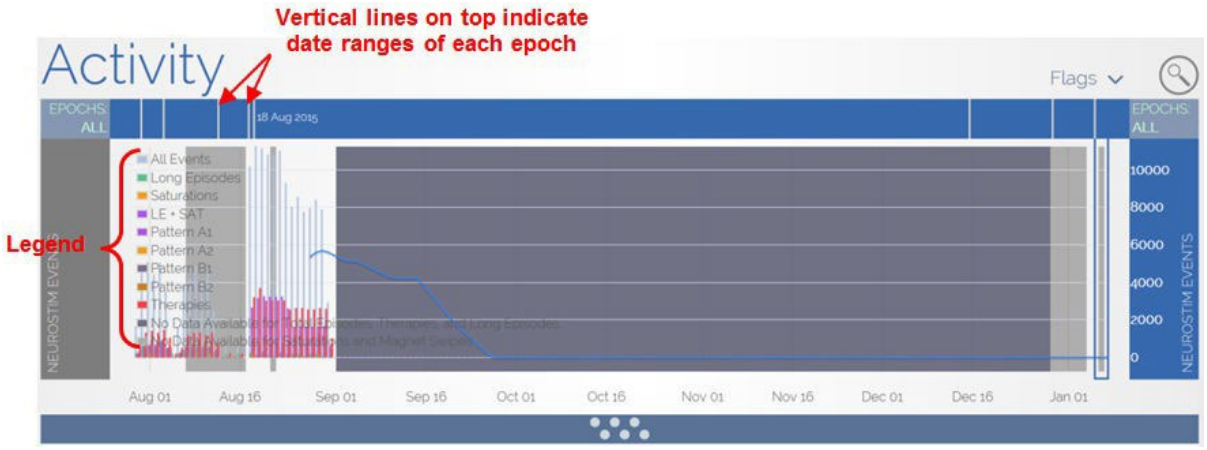


Figure 26 Activity histogram with all events showing and supporting legend on left

Within the clinical care workflow, it is recommended to review Detection History using the histogram view. Specific events of interest may be important when assessing the patient's seizure history. Using the drop lists allows for these events to be displayed in categories, such as long episodes, pattern A, pattern B, responsive therapy, or saturation.

Specific time periods may be of interest and additional information may be obtained by selecting the magnify button in the upper right corner. Click and drag across histogram to review the time period of interest.

Figure 27 Use the magnify button to view a portion of activity in larger size

VIEW NEUROSTIM SETTINGS

Within the clinical care workflow, it is recommended to review previously programmed settings.

The lower part of the **ACTIVITY** screen details the history of detection and stimulation settings used—collectively called **NEUROSTIM SETTINGS**—between each iteration of programming (each programming epoch), which are in rows from most recent on top to oldest on the bottom. Drag up the gray separator bar with six dots to view more of these settings, which will cover the upper histogram portion. Scroll down on the setting rows to view more rows, if they are present.

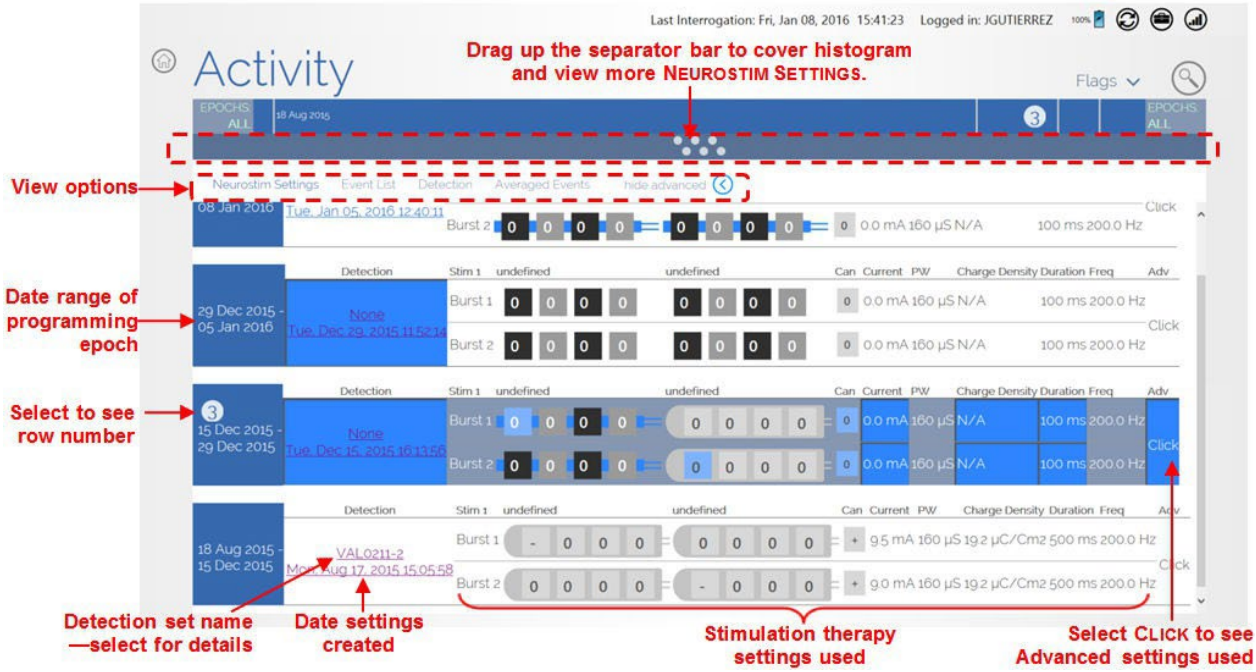


Figure 28 ACTIVITY screen—view detection and stimulation settings used between programming sessions

At the left end of each row is a blue tile showing the date range when those **NEUROSTIM SETTINGS** were used. Vertical lines above the histogram correspond to these dates. When you select a blue tile, its row number appears on the tile. Row numbers increase as you go down.

Also, the corresponding time period is bracketed in the histogram graph, and the row number and start date appear over the bracketed time period, if there is enough room on screen. This helps to relate the programming changes to the device activity.

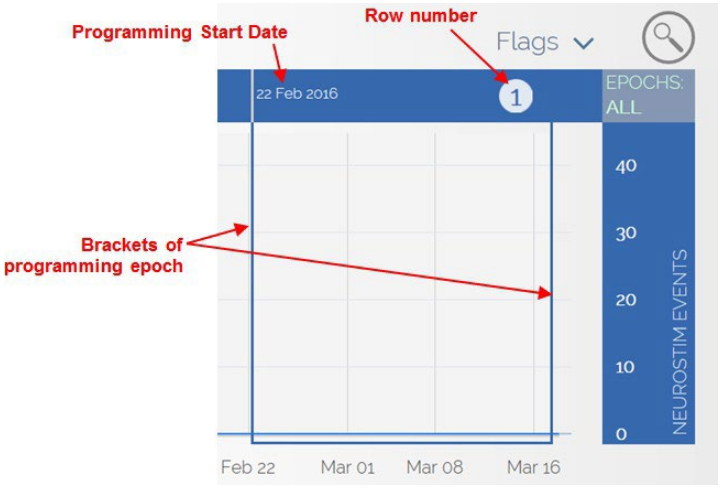


Figure 29 Activity histogram excerpt showing programming epoch 1 bracketed

Next to the blue tiles on the **ACTIVITY** screen, the second column shows the name of the **PROGRAMMING SET**. Select the name to view its details in the screen that opens. Touch the circle-X (exit) button at upper right to close.

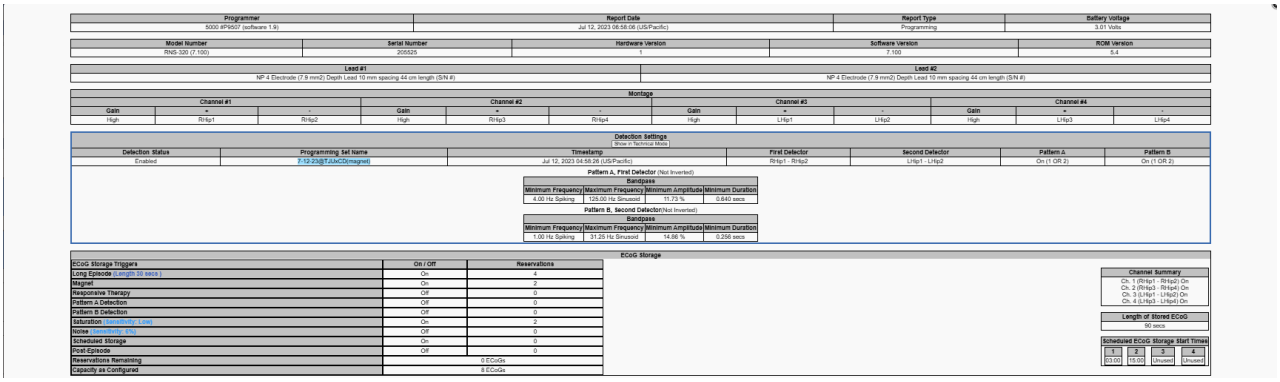


Figure 30 Programming set details

At the right end of each row on the **ACTIVITY** screen is the **ADV** (Advanced) column. Touch **CLICK** below **ADV** to view the advanced stimulation therapy settings used in that programming epoch in the **THERAPY 1 ADVANCED SETTINGS** screen. Touch the circle-X (exit) button at upper right to close.

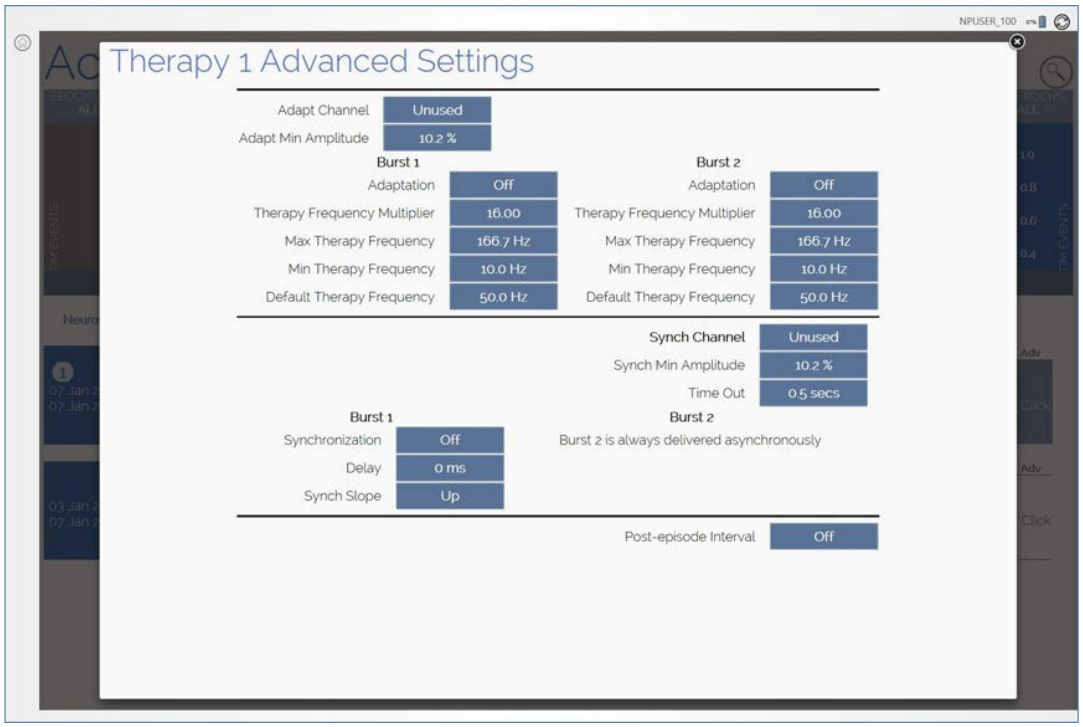


Figure 31 View Advanced Stimulation Therapy Settings

VIEW EVENT LIST

On the **ACTIVITY** screen, select **EVENT LIST** next to **NEUROSTIM SETTINGS** above the left end of the row to see a complete list of events for all rows. From there, select links under **REPORT TYPE** for detailed reports on each event. Scroll up or down to see the event list and to scroll between programming epochs.

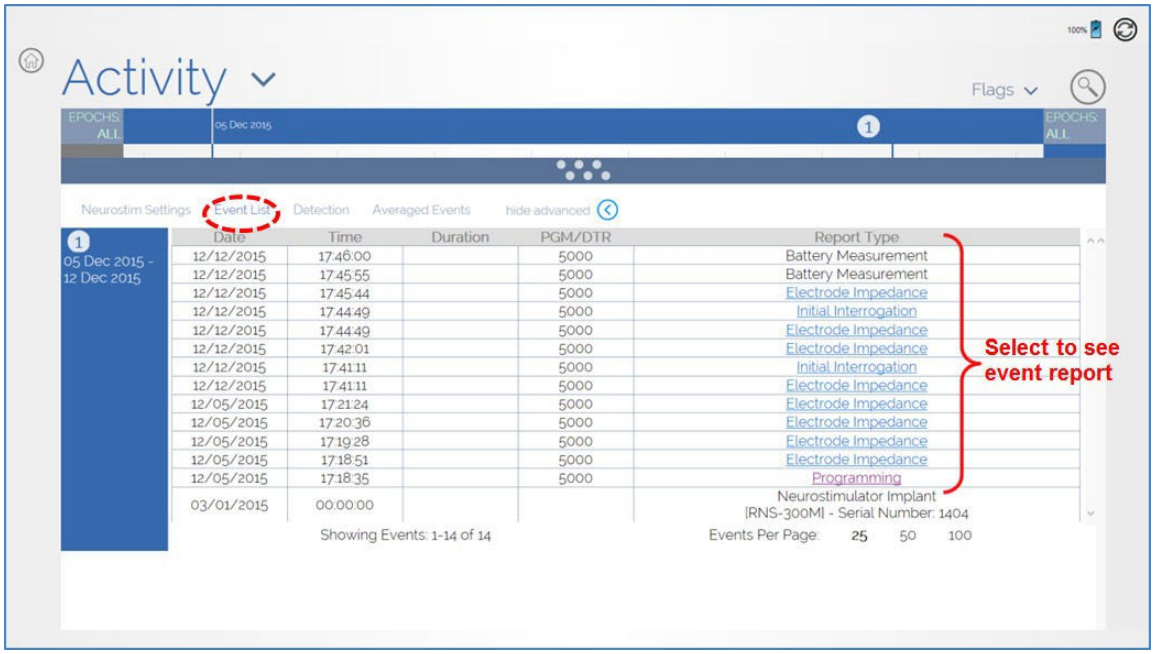


Figure 32 Event List selected - lists all events in a Neurostim Settings period, with links to reports

Types of Reports

There are six types of patient reports:

- **Interrogation** (Initial or Subsequent within the programmer session) > Interrogation time/date
  - Programmed Neurostimulator settings
  - Event counters (# of detections, stimulations, etc.)
  - Event date/time and details
- **Programming**
  - Programming date/time
  - Programmed Neurostimulator settings
- **Electrode Impedance**
  - Impedance measurement date/time
  - Impedance measurement of each electrode (in ohms)
- **Battery Measurement**
  - Battery measurement date/time
  - Battery measurement value (in volts)
- **Therapy Testing** (shows therapy testing values)

- **ECoG**
  - ECoG trigger time/date
  - ECoG record
  - ECoG trigger reason
  - ECoG markers (detections, stimulations, etc.)

Advanced Views

DETECTION, **AVERAGED EVENTS** and **PROGRAMMING EPOCHS** are the advanced views. **DETECTION** shows a graph of detection occurrence percentage for each programmed detection pattern since the last change in detection settings. **AVERAGED EVENTS** shows a week by hour histogram of the normalized average number of detected episodes per hour for the last 12 weeks. **PROGRAMMING EPOCHS** shows the history of recent programming epochs, summarizes the settings and activity of each epoch, and highlights the changes in settings and activity from one epoch to the next.

CREATE A PROGRAMMING SET

Change Settings: ECoG Capture, Detection, and Stimulation

A programming set includes the settings for detection, stimulation, and ECoG capture. You can change each kind of setting separately or in any combination, but all three kinds of settings are saved as part of a programming set. For instructions, refer to the following sections.

- *Configure ECoG Capture* on page *48*
- *Configure Detection: Define and Modify Detection Settings* on page *52*
- *Configure Responsive Therapy* on page *62*

Review and Save Changes

Having made changes to detection, stimulation or ECoG capture settings, those changes must be carefully reviewed and then saved. When saving completes, all the individual changes are packaged into a single programming set.

1. While working on the PDMS (outside an interactive programming session), select **REVIEW ALL CHANGES**, which returns you to the **PROGRAMMING SETS** screen and shows all **PENDING PROGRAMMING CHANGES**. Scroll down if necessary to see all the changes.

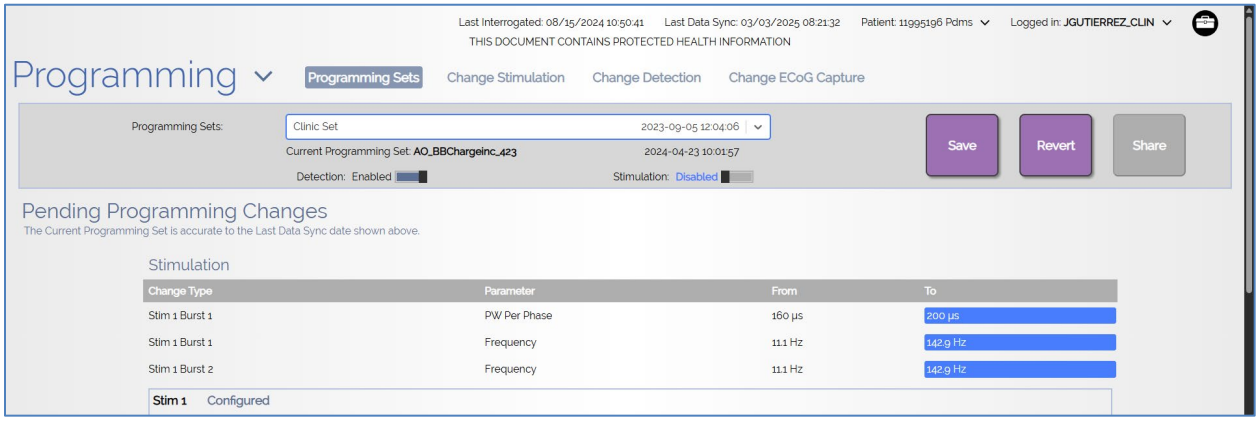


Figure 33 Pending programming set ready to be saved

- 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.
- Back in the **PROGRAMMING SETS** screen, the **SAVE** and **REVERT** buttons are now active. To remove all changes to the programming set, select **REVERT**. The **REVERT PROGRAMMING SETTINGS** dialog opens. Select **REVERT** to confirm your choice, or **CANCEL** to go back.

2. Select **SAVE** and name the programming set in the **SAVE PROGRAMMING SET** dialog that opens, and then select **SAVE** in the dialog.

Figure 34 Save Programming Set dialog

When saving is complete, you return to the **PROGRAMMING SETS** screen and the **SHARE** button is active. This new programing set will not be available to users and programmers until it is actively shared with them. A programming set becomes available for offline programming when it is shared and then downloaded locally to the programmer.

SHARE A PROGRAMMING SET

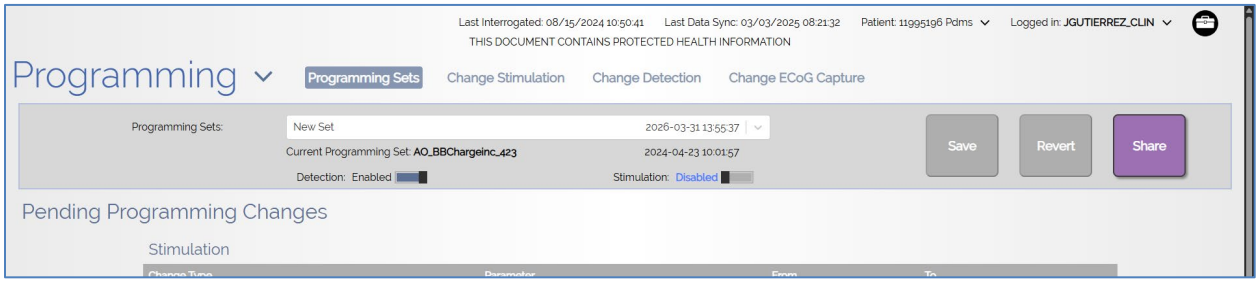


Figure 35 Share button active on Programming Sets screen

1. You can share the currently selected programming set by selecting the active **SHARE** button on the **PROGRAMMING SETS** screen. (The **SHARE** button will not be active if the selected programming set has already been programmed to the neurostimulator.) The **SHARE PROGRAMMING SET** dialog opens.

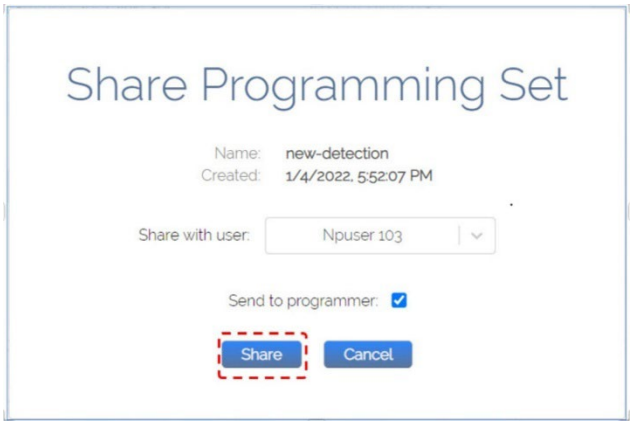


Figure 36 The Share Programming Set dialog on the PDMS on a web browser

2. You can select available checkboxes in any combination to share according to these options:
   a. **SHARE WITH USER:** to share with a specific user, who could then access it on any programmer to which he is logged in. Touch the field to select from a list of available usernames, if any. (Available usernames would include those users authorized for access to the patient to which the programming set applies.)
   b. Send to programmer: Select to share with any programmer used to interrogate the neurostimulator associated with the patient to which the programming set applies. This is the target patient's neurostimulator.
3. When you have selected a user or programmer or both to share with, select the **SHARE** button in the **SHARE PROGRAMMING SET** dialog.

When sharing completes, a message on the dialog reports **PROGRAMMING SET SHARED SUCCESSFULLY**. Click **OK** to close the dialog and return to the **PROGRAMMING SETS** screen.

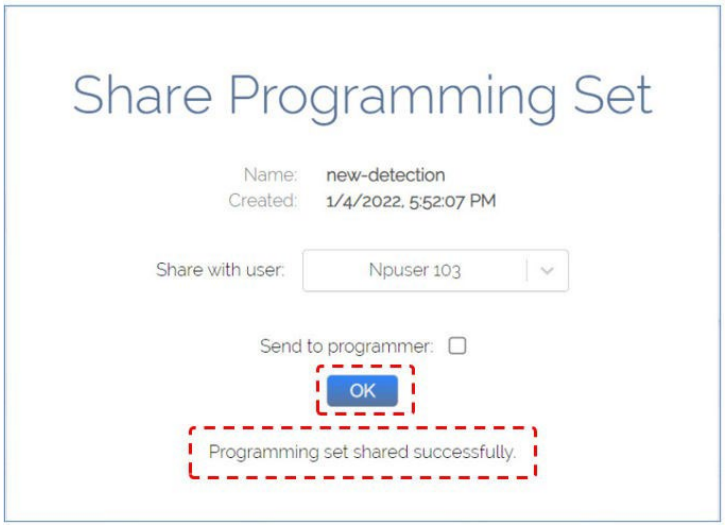


Figure 37 Example message reporting successful sharing

USING PROGRAMMING SETS

DESCRIPTION OF PROGRAMMING SETS

PROGRAMMING SETS OVERVIEW

The RNS Neurostimulator is a highly flexible system that can be configured to detect specific patterns of electrographic activity, deliver responsive stimulation, and record electrocorticographic (ECoG) data in response to defined events. A programming set is the primary mechanism for implementing these configurations on the neurostimulator.

A programming set conveniently packages and documents changes to:

- Detection settings
- Stimulation delivery settings
- ECoG capture settings

Programming sets are typically created on the PDMS as part of the clinical workflow, following patient data review and treatment planning. Once finalized, the programming set can be wirelessly transmitted to the RNS Programmer, which is then used to apply the changes to the neurostimulator during an interactive programming session.

Programming sets are comprehensive and provide a structured, efficient way to customize therapy based on patient-specific needs.

DETECTION TOOLS AND DETECTORS

Detection tools and detectors support you as you exercise clinical judgment to define detection settings. Detectors and settings initially suggested by the software (as described in *Phase 2: Define Detection Settings* on page *54*) offer a starting point only. The software does not preempt nor replace your clinical judgment.

When you select a waveform pattern to detect, the SimpleStart Feature suggests a detector (one of **LINE LENGTH**, **RHYTHMIC ACTIVITY** or **SPIKE ACTIVITY**) and associated settings as a proposed fit for that pattern. You use this procedure initially (in *Phase 2: Define Detection Settings* on page *54*) to create new detection settings when you have first gathered ECoGs containing the type of activity you wish to detect. The software also simulates the behavior of the suggested detector on those ECoGs you have selected from all of the patient's stored ECoGs. By reviewing the simulated detection on an ensemble of stored ECoGs, you can confirm that detection occurs when desired, or change the selected pattern, detectors and/or settings to make detection occur when desired. Having defined up to four detection patterns and associated settings, you then save these detection settings as part of a programming set.

The RNS Neurostimulator uses three kinds of detection tools: **LINE LENGTH** or **POWER CHANGE** (see *Power Change Detector* on page *40*), **BANDPASS** (see *Bandpass Detection Tool* on page *44*), and **AREA** (see *Area Detection Tool* on page *45*).

- The **LINE LENGTH** detection tool is used in the **POWER CHANGE** detector.
- The **BANDPASS** detection tool is used in two detectors, **RHYTHMIC ACTIVITY** and **SPIKE ACTIVITY**.
- The **AREA** detection tool is infrequently used and can be selected only manually from the **DEFINE PATTERNS** dialog (select **MORE CONTROLS > ADV SETTINGS**).

Note: ***Rhythmic Activity*** *and* ***Spike Activity*** *are both types of ECoG activity that can be detected by the* ***Bandpass*** *tool. The* ***Area*** *tool is not used to generate a suggested detector from an ROI, but can be manually programmed by selecting* ***More Controls > Adv Settings****.*

The table below summarizes this information.

Table 2 Detection Tools and Detectors Used With

Detection Tool	Detectors Used With
Power Change (formerly Line Length)	Power Change (or Line Length)
Bandpass	Rhythmic Activity and Spike Activity
Area	Area (configured manually only, not used as a suggested detector)

Power Change Detector

To understand how the Power Change Detector works refer to *Figure 38* below. Imagine the ECoG as a string that can be stretched so the length can be measured. ECoGs with higher amplitude or frequency oscillations will have longer length.

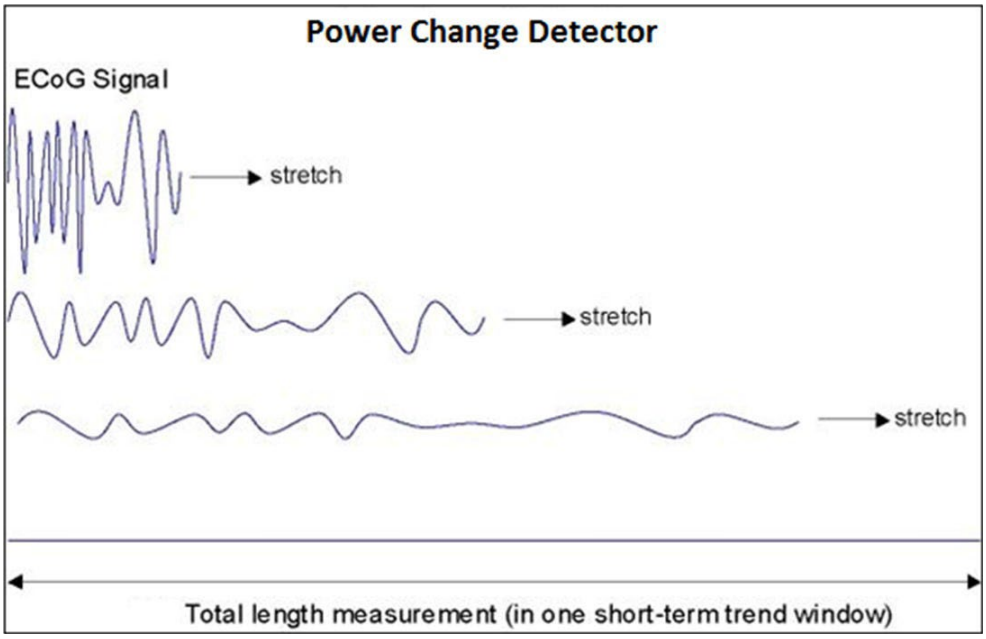


Figure 38 An illustration of the Power Change (or Line Length) detector

The ECoG in the bottom of *Figure 39* below shows a developing seizure and the corresponding short-term (red) and the long-term (blue) power trend lines. The power change detector works by comparing the short-term trend window (red, typically 1 to 4 seconds) to the long-term trend window (blue, typically 1 to 2 minutes).

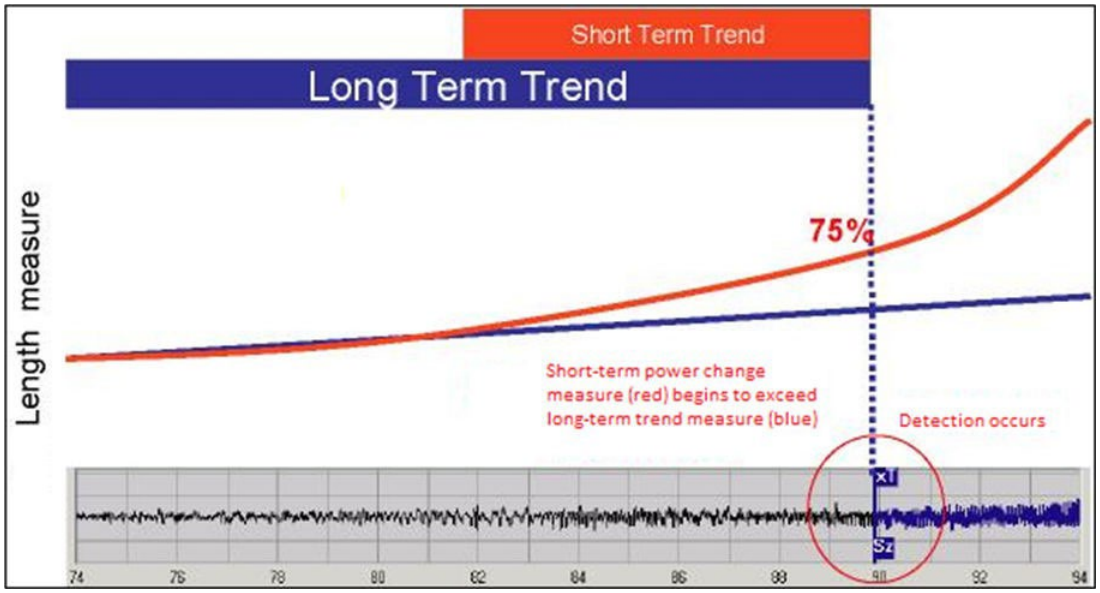


Figure 39 Power Change detector example

Detection occurs when the difference between the short-term and long-term trend windows exceeds a programmed **SENSITIVITY** percentage (typically 37.5% to 100%). Lower **SENSITIVITY** settings result in earlier and more frequent detections. The **DETECT** setting specifies the length of the short-term trend (in seconds). Shorter **DETECT** settings result in earlier and more frequent detections.

RHYTHMIC ACTIVITY DETECTOR

The Rhythmic Activity detector provides highly specific and early detection of rhythmic activity within a defined bandpass. It acts like a frequency filter and can therefore be used to detect activity within specific frequency bands (theta, alpha, beta, and gamma). To understand how the Rhythmic Activity detector works refer to *Figure 40* below.

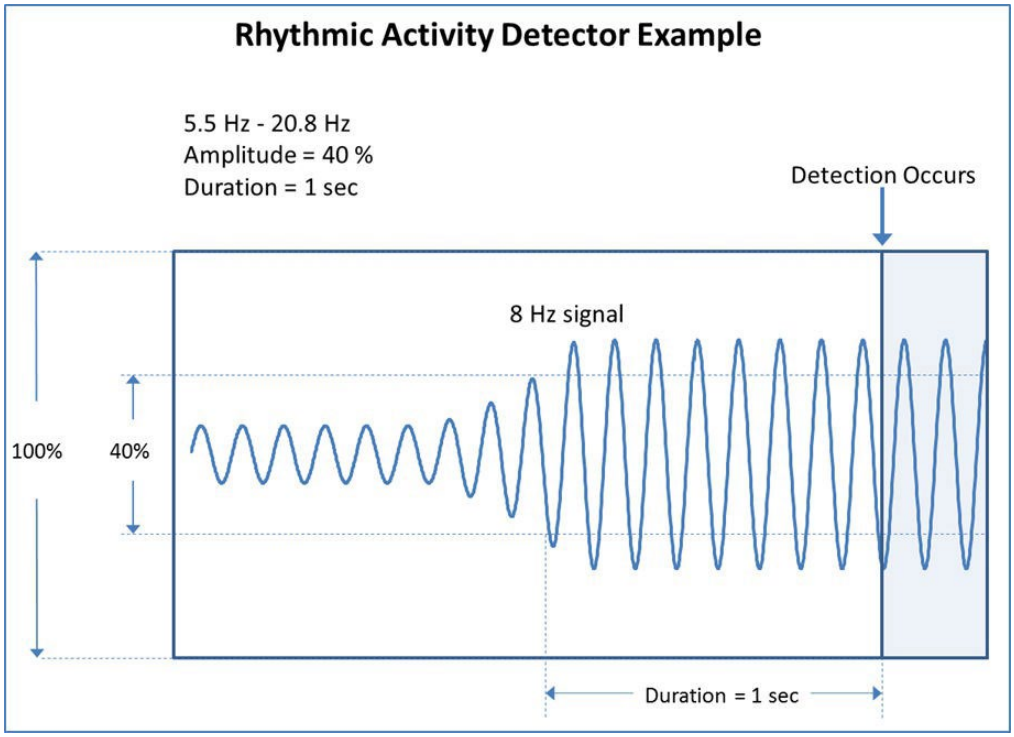


Figure 40 Rhythmic Activity detector example

The Rhythmic Activity detector analyzes the ECoG to determine when a signal is present within a specified bandpass that meets specified amplitude and duration requirements. Four configurable parameters define the Rhythmic Activity detector operation: the **MINIMUM FREQUENCY** and **MAXIMUM FREQUENCY** that define the bandpass, the **AMPLITUDE**, and the **DURATION**. Detection occurs when a signal within the bandpass exceeds the **AMPLITUDE** for the minimum **DURATION**. As **DURATION** is increased, the detector becomes less sensitive because it will take longer for a signal within the bandpass to be detected. As **AMPLITUDE** is increased, the detector becomes less sensitive because lower amplitude signals will not qualify.

SPIKE ACTIVITY DETECTOR

The Spike Activity detector functions in a manner very similar to the Rhythmic Activity detector, but it is optimized for the faster transients that comprise spikes. To understand how the Spike Activity detector works refer to *Figure 41* below.

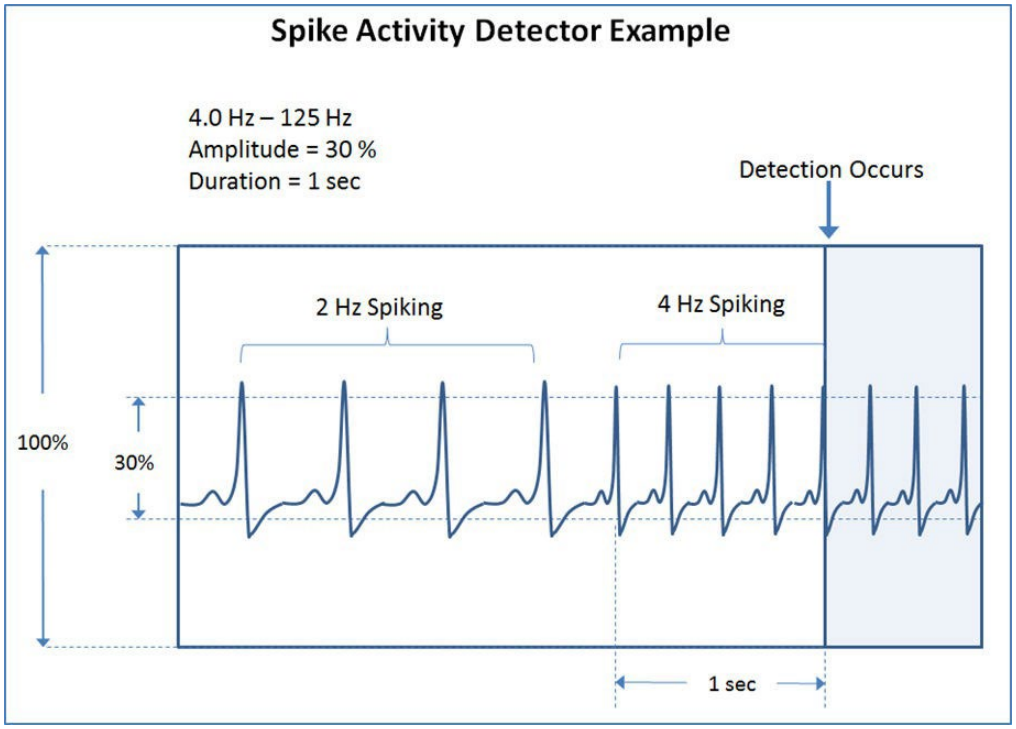


Figure 41 Spike Activity detector example

The Spike Activity detector analyzes the ECoG to determine when a signal is present within a specified bandpass that meets specified amplitude and duration requirements. Four configurable parameters define the Spike Activity detector operation: the **MINIMUM FREQUENCY** and **MAXIMUM FREQUENCY**, the **AMPLITUDE**, and the **DURATION**. The **MINIMUM FREQUENCY** defines the slowest spiking rate that can be detected. The **MAXIMUM FREQUENCY** defines the upper frequency limit of the passband for the detector. Because the signal frequency content of the fast transient portions of spikes are generally much higher than the spike rate, the **MAXIMUM FREQUENCY** usually needs to be set much higher than the spike rate. Detection will occur when spikes meeting the frequency requirements also exceed the **AMPLITUDE** for the **DURATION**. As **DURATION** is increased, the detector becomes less sensitive because it will take longer for detection to occur.

BANDPASS DETECTION TOOL

The Bandpass detection tool provides highly specific and early detection of rhythmic and spiking activity. It acts like a frequency filter and can therefore be used to detect activity within specific frequency bands (for example, theta, alpha, beta, and gamma). The **RHYTHMIC ACTIVITY** and **SPIKE ACTIVITY** detectors use the Bandpass tool.

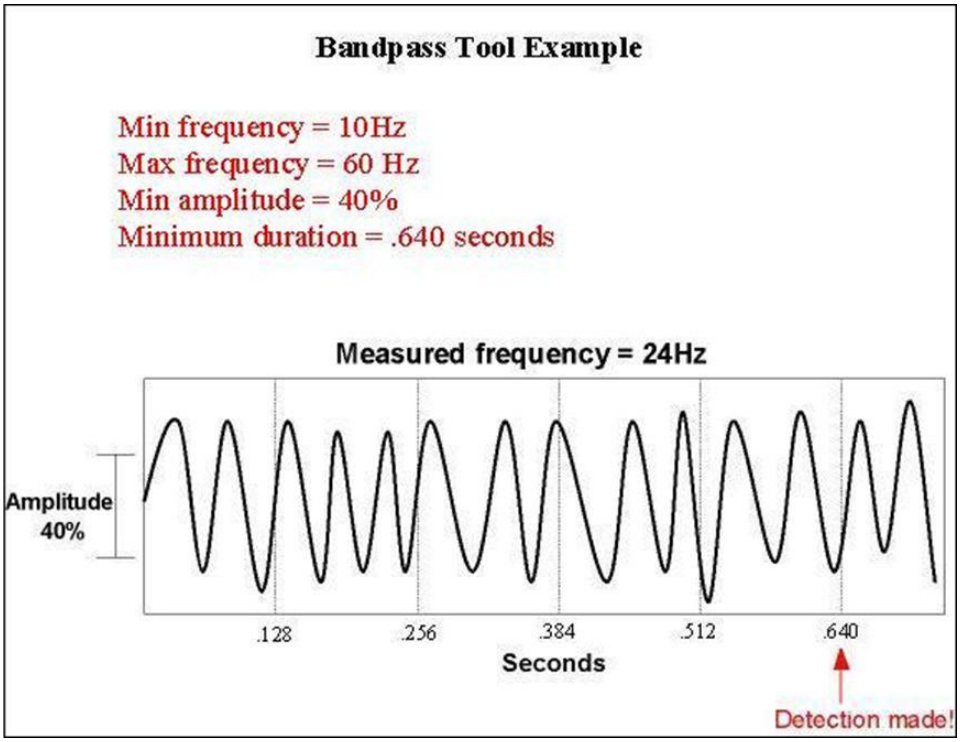


Figure 42 Bandpass detection tool example

AREA DETECTION TOOL

The **AREA** detection tool can be selected only manually from the **DEFINE PATTERNS** dialog (select **MORE CONTROLS > ADV CONTROLS**). It is not used as a suggested detector by the software. The **AREA** detection tool measures the area between the ECoG and the time axis.

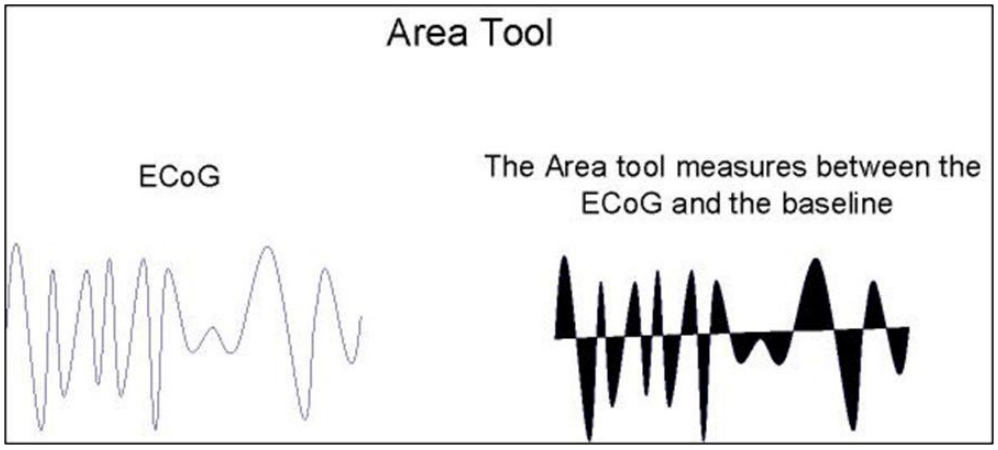


Figure 43 An illustration of the Area Tool detector

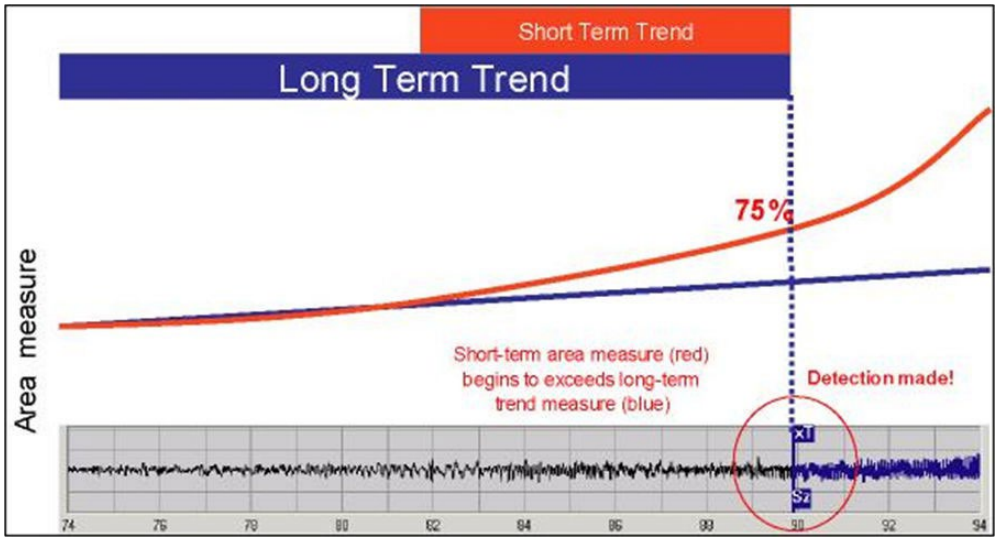


Figure 44 Area detection tool example

The **AREA** detector operates by comparing the ECoG area (area per second) in a short-term trend window (typically 1 to 4 seconds) to the ECoG area in a long-term trend window (typically 1 to 2 minutes). Detection occurs when the difference between the short-term and long-term trend windows exceeds a programmed threshold (typically 37.5% to 100%).

Overview of Responsive Therapy

The RNS Neurostimulator can deliver a therapy sequence of up to 5 individually configured therapies in response to detected activity. The neurostimulator resumes sensing after each therapy is delivered. If the activity is still detected, the next (sequential) therapy is delivered. If the activity is no longer detected, the remaining therapies are not delivered and the episode ends. Therapy sequence refreshes with the detection of each new episode.

The system enables you to configure behavior for the first therapy in one of two ways:

- You can select a unique burst to be delivered in response Pattern A detection and a different unique burst to be delivered to Pattern B detection.
- You can select up to two bursts to be delivered in response to any event detector.

All subsequent therapies deliver a maximum of 2 bursts and are independent of the specific event detector.

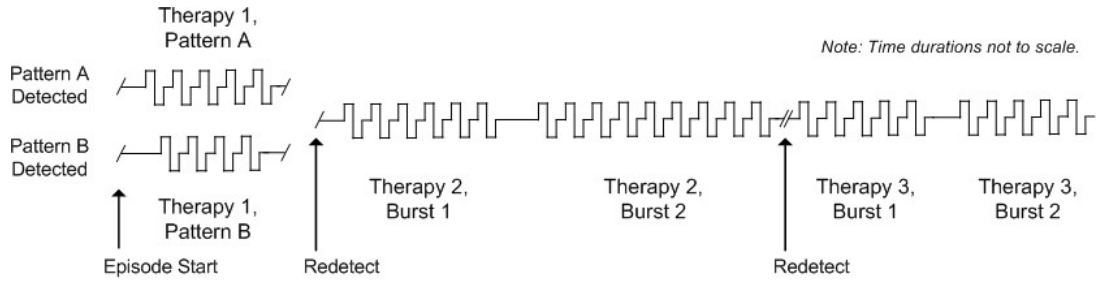


Figure 45 A Therapy Sequence Delivered in Response to a Specific Event Detector

Therapy 1 is configured to deliver a single burst in response to a specific detector. In this example, Pattern A is detected at the episode start; Therapy Pattern A burst is delivered. If Pattern B is detected at the episode start, Therapy Pattern B burst is delivered. Subsequent therapies, Therapy 2 and Therapy 3, are configured to deliver 2 bursts each, no matter which pattern is subsequently detected.

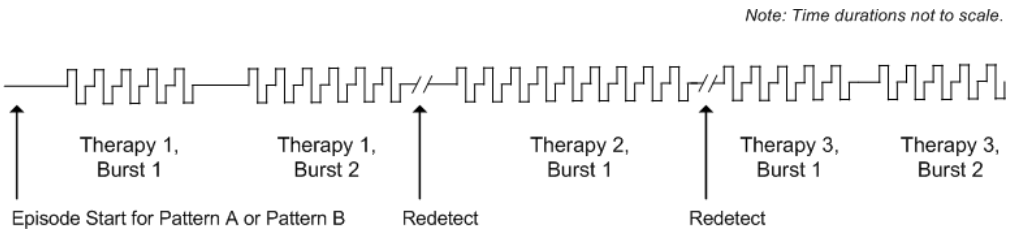


Figure 46 A Therapy Sequence Delivered in Response to any Event Detector

Therapy 1 is configured to deliver Burst 1 and Burst 2 in response to any event detector. In subsequent therapies, Therapy 2 is configured to deliver Burst 1 only and Therapy 3 is configured to deliver Burst 1 and Burst 2.

The following figure identifies the parameters of a burst of stimulation therapy.

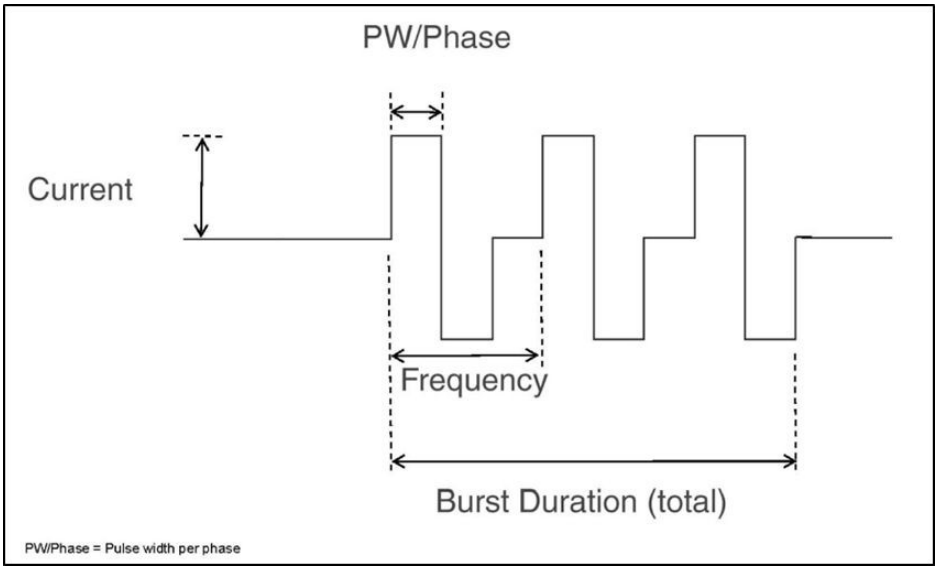


Figure 47 Parameters of a single burst of stimulation

CREATING PROGRAMMING SETS

OVERVIEW

- A programming set includes the programmable neurostimulator settings for ECoG capture, detection, and stimulation. You can change each kind of setting separately or in any combination, but all three kinds of settings are saved as part of a programming set. After implant, creating the initial programming set usually entails setting up detection and ECoG capture to gather ECoGs with epileptiform patterns. Stored ECoGs are then analyzed and used to configure detection settings and to adjust ECoG capture settings, leading to increasingly customized programming sets for the patient. Once you have established which patterns to detect and respond to with therapy, programming set creation includes setting up and enabling stimulation therapy. It is recommended that you create a programming set using the PDMS on a browser and then share it to programmers; however, you can create or

modify the programming set on the programmer directly. See the following sections for instructions to create or modify the elements of a programming set:

- *Configure ECoG Capture* on page *48*
- *Configure Detection: Define and Modify Detection Settings* on page 52
- *Configure Responsive Therapy* on page *62*

A programming set created using the PDMS via a personal computer, as recommended, is not accessible on a programmer unless it is shared or downloaded. See *Making a Programming Set Available for Programming* on page *68*.

CONFIGURE ECOG CAPTURE

An electrocorticogram (ECoG) can be stored by the RNS Neurostimulator when an ECoG capture trigger occurs. The maximum number of ECoGs that can be stored is affected by the number of channels selected ON for storage, and the pre-trigger and post-trigger durations. The oldest stored ECoGs are continually replaced by the newly stored ECoGs, except as noted below.

The number of ECoGs stored for a particular ECoG capture trigger can be reserved. Reserved ECoGs are only overwritten by newer ECoGs of the same ECoG capture trigger type.

ECoG capture may also be scheduled at four different times on a 24-hour clock.

SELECTING ECOG CAPTURE SETTINGS

Figure 48 Select Programming tile on the Home screen

1. Select **PROGRAMMING** from the PDMS **HOME** screen.
2. On the **PROGRAMMING** screen, select **CHANGE ECOG CAPTURE** at upper right.

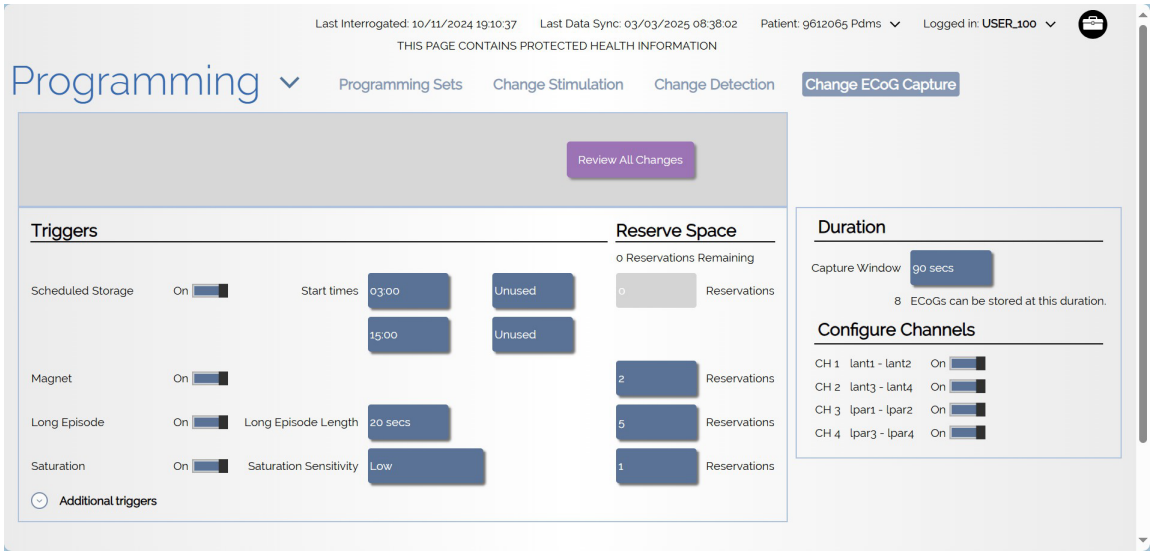


Figure 49 Change ECoG Capture screen

3. **Turn On Desired Channels:** In the **CONFIGURE CHANNELS** area at right, select the **ON/OFF** switch next to the desired **CHANNEL(S)** (**CH 1** through **CH 4**) to turn each channel on or off as desired. Only the channels selected **ON** will be recorded and stored.
4. **Set Capture Duration:** In the **DURATION** area at upper right select the **CAPTURE WINDOW** field and select one of the capture duration options. After your selection, the **DURATION** area shows the total duration (in seconds) and the number of ECoGs that can be stored at this duration.
5. **Set Capture Triggers:** In the **TRIGGERS** area at upper left, select the **ON/OFF** switch to turn **ON** the triggers that you wish to initiate ECoG capture.

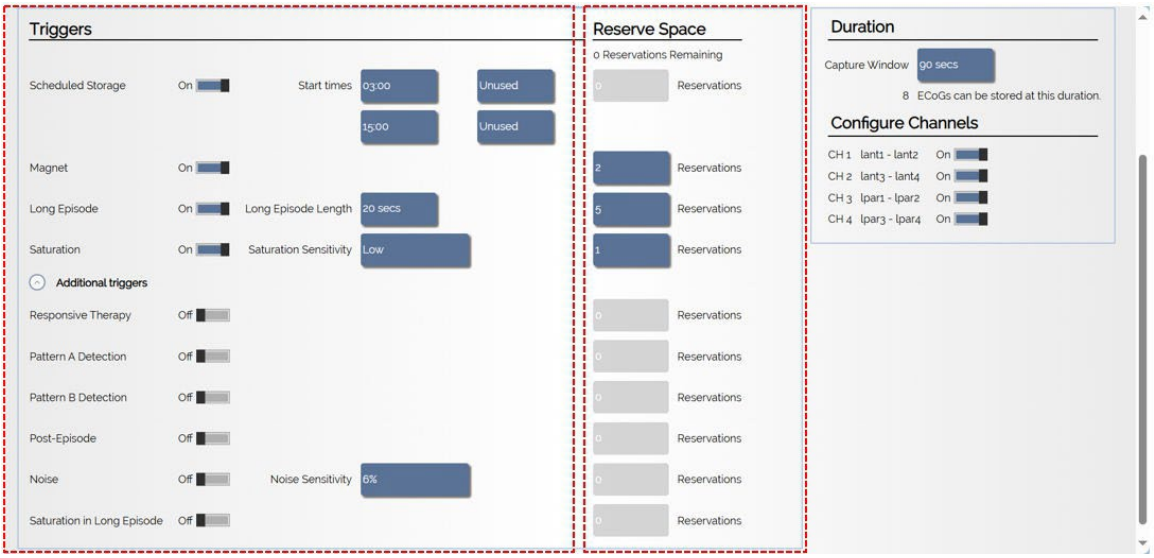


Figure 50 Selecting ECoG Capture Triggers

Commonly Used Triggers: The more commonly used triggers are listed first.

- **SCHEDULED STORAGE**: Initiate ECoG capture at up to four specific start times, which you can select using the fields to the right. Options are available in ten minute intervals using 24 hour time.
- **MAGNET**: Initiates ECoG capture when the patient swipes the magnet over the neurostimulator. If the patient swipes the magnet when they experience clinical symptoms, selecting this trigger may be helpful in evaluating these events.
- **LONG EPISODE**: Initiates ECoG capture when a detected episode exceeds the duration you select in the **LONG EPISODE LENGTH** field to the right. Duration options range from 1 to 120 seconds.
- **SATURATION**: Initiates ECoG capture when the ECoG amplitude exceeds the threshold associated with the value you select in the **SATURATION SENSITIVITY** field to the right. The sensitivity options are **High**, **Medium**, **Low** and **Off**. Selecting this trigger may be helpful in troubleshooting the RNS System.

ADDITIONAL TRIGGERS: Select the down arrow next to **ADDITIONAL TRIGGERS** at lower left to access the triggers below.

- **RESPONSIVE THERAPY**: Initiates ECoG capture when electrical stimulation therapy is delivered in response to a detected event. Selecting this trigger may be helpful in determining if therapy was delivered appropriately as well as evaluating the result of therapy delivered.
- **PATTERN A DETECTION** and **PATTERN B DETECTION**: These are separate triggers; each initiates ECoG capture when a detected episode begins with the patterns designated as Pattern A and Pattern B on the **PATTERN DETECTION** screen. Selecting a pattern trigger may be helpful in evaluating the pattern detection settings.
- **POST-EPISODE**: Initiates ECoG capture at the end of a detected episode. Selecting this trigger may be helpful in evaluating activity after an episode.
- **NOISE**: Initiates ECoG capture when the ECoG signal exceeds 60 Hz. Selecting this trigger may be helpful in troubleshooting the RNS System.
- **SATURATION IN LONG EPISODE**: Initiates ECoG capture when the ECoG amplitude exceeds the threshold selected in the **SATURATION SENSITIVITY** field during an episode that exceeds the duration selected in the **LONG EPISODE LENGTH** field.

6. **Set Reservations for Each Trigger:** In the **RESERVE SPACE** column to the right of each trigger (see figure above), select the **Reservations** field and select the number of reservations to make for each trigger. A reservation means that up to the specified number of ECoGs will be stored for that trigger, and can only be overwritten by newer ECoGs of the same trigger type. The total number of reservations available depends on the duration selected in the **DURATION** area at upper right.
7. Follow the instructions to *Create a Programming Set* on page *35*.

RECOMMENDED INITIAL ECOG CAPTURE SETTINGS

There are three recommended ECoG triggers to be programmed at implant, though they can be programmed later after creating a programming set using PDMS on a browser. 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.

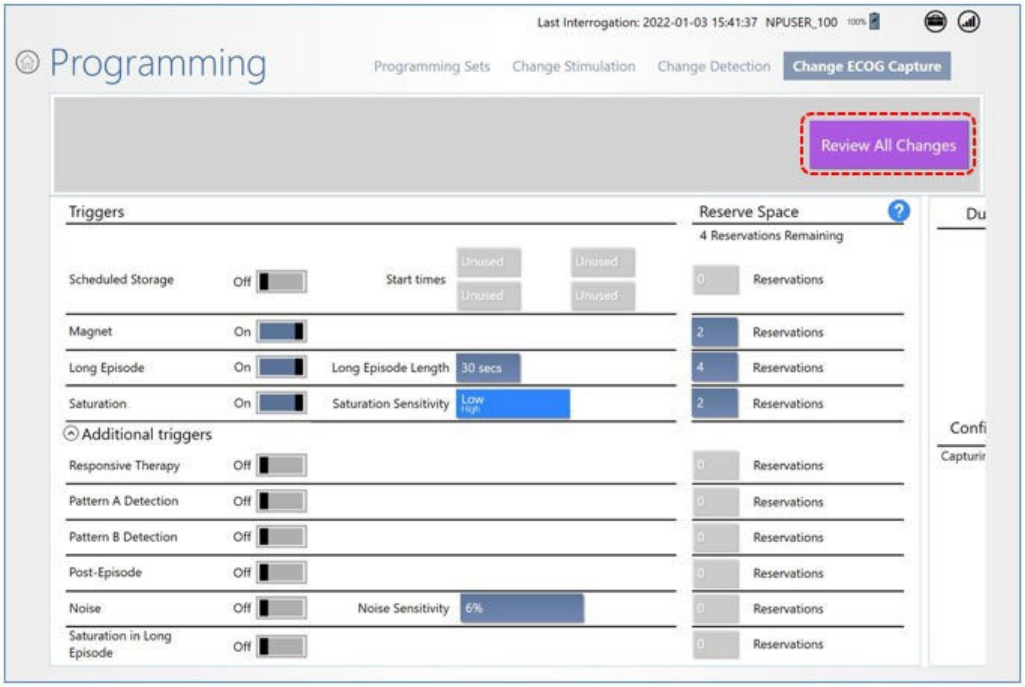


Figure 51 Recommended Initial ECoG Capture settings

- **Configure Channels for Capturing:** All four channels ON
- **Duration:** 90 SECS
- **Triggers On for ECoG Capture:**
  - **MAGNET**: Reservations = **2**
  - **LONG EPISODE**: Reservations = **4**, Long Episode Length = **30 SECS**
  - **SATURATION**: Saturation Sensitivity: **LOW**, Reservations = **2**
  - All other triggers **OFF**

RECOMMENDATION FOR REVIEW OF INITIAL ECOG CAPTURE SETTINGS

ECoGs stored by the RNS Neurostimulator during the first several days after implantation of the neurostimulator and leads may not be representative of the patient's typical baseline activity. ECoG capture settings should be reviewed to ensure that the desired activity is being stored. If it appears that ECoGs containing the desired activity are being overwritten by later events, instruct the patient to use the remote monitor and wand to interrogate the neurostimulator immediately after each clinical seizure, or to interrogate several times per day. Several interrogations per day during the first several days after implantation will not have a significant impact on battery life.

- **RECOMMENDATION**: Review ECoGs on the PDMS to determine whether detections and storage are optimal. If not, consider adjustments to the following triggers recommended to be **ON** initially.
- **LONG EPISODE LENGTH**: Adjust the duration that triggers capture of a long episode.
- **MAGNET**: Consider turning **OFF** the **MAGNET** trigger if the patient is not able to apply the magnet before or immediately after a clinical seizure, or if ECoGs captured by this trigger are not useful. Magnet swipes will still be counted and reported in the diagnostics.
- **DURATION**: Select a briefer **CAPTURE WINDOW** value to yield more stored ECoGs, or a lengthier value to yield fewer stored ECoGs.

CONFIGURE DETECTION: DEFINE AND MODIFY DETECTION SETTINGS

A programming set includes the settings for detection, stimulation, and ECoG capture. Detection settings are used by the RNS Neurostimulator to recognize epileptiform activity as defined by the physician. To configure detection means to select specific ECoG patterns to be detected, and then to program the system to detect these patterns. Configuring pattern detection is a prerequisite for electrical stimulation therapy, but it does not necessitate enabling therapy. To understand the options for configuring pattern detection, see *Detection Tools and Detectors*.

Configuring pattern detection has three phases:

- *Phase 1: Choose Default Detection Settings* on page *53*, you select one of the three default detection sets to gather an initial collection of ECoGs. This is usually configured and programmed in the operating room immediately after implantation.
- *Phase 2: Define Detection Settings* on page *54*, after initial ECoGs have been stored, you review the stored ECoGs and identify the specific ECoG patterns to be detected. Using the SimpleStart Feature and ECoG Assistant functionality, the system provides a starting point for this process. These tools are to assist you as you exercise clinical judgment to define detection settings. It suggests a starting point only. It does not preempt nor replace your clinical judgment. This is usually programmed at the first visit post-implantation.
- In *Phase 3: Customize Detection* on page *57*, you repeat the process of reviewing stored ECoGs and adjusting the parameters of each pattern to optimize detection of ECoG activity for this patient. This is programmed at any visit after phase 2.

To Put These Three Phases In Context:

Immediately after implantation of the neurostimulator, you select a default detection set in **Phase 1**, in order to collect ECoGs with activity of interest specific to the patient, and ECoGs with baseline activity.

After collecting sufficient ECoGs, you identify the specific electrocorticographic patterns to be detected and then, in **Phase 2**, the system provides a starting point for establishing patient-specific detection settings.

You may then modify the parameters of the suggested starting detection settings to make detection more or less sensitive, or to detect earlier or later.

In future visits, after collecting additional ECoGs, you then, in **Phase 3**, iterate to improve detection (and, once responsive therapy has been enabled, to improve clinical response) by making small, incremental changes to detection parameters with the sliders or **More Controls**.

> ***Note:*** *Typically, physicians repeat earlier phases (Phase 1 or Phase 2) only if they observe a new type of ECoG activity of interest that requires an additional detector; or if a good clinical response has not been obtained and they wish to start over.*
>
> ***Note:*** *You must use the PDMS to identify and select ECoG patterns to detect. PDMS can be accessed via a web browser or on the programmer via the Patient List. When you select a pattern, the PDMS automatically simulates detection on all ECoGs stored for a patient. Simulation is displayed for groups of six ECoGs at a time, and you can navigate through all ECoGs for that patient.*
>
> ***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.*

Phase 1: Choose Default Detection Settings

Upon first use of the programmer for each patient, the patient has no saved ECoGs from which to select a pattern for detection, and so you must select one of three default programming sets. This is usually configured in the operating room immediately after implantation. The default sets are used to gather an initial set of ECoGs for a patient, which you can then use in a subsequent visit to define detection settings specific to the patient. If you have already performed these steps once, proceed to the next section, *Phase 2: Define Detection Settings* on page *54*.

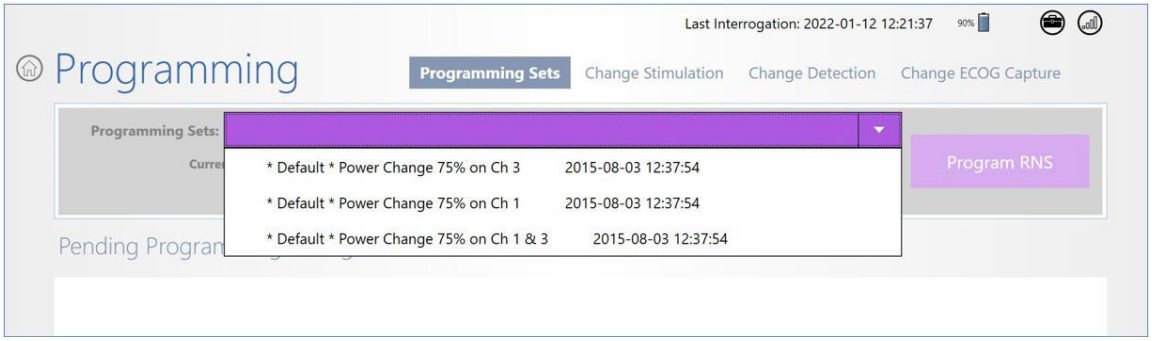


Figure 52 Select default detection settings

Choose one of the three default programming sets, which includes default detection settings. In the usual case, a patient has two active leads to be configured, and therefore the recommended default pattern is Power Change 75% on CH 1 & 3 (Default). (If only one lead is implanted, this two-channel option will not be available.) The other default patterns detect on only one lead.

Power change 75% is a detection setting that captures any large changes in the signal that clinicians can program and optimize as detection patterns. For detailed instructions, see *Program Default Detection Settings* on page *99*.

PHASE 2: DEFINE DETECTION SETTINGS

Note: *For this phase, use the PDMS via web browser on a personal computer. Detection settings are saved as part of a new programming set.*

At this point, the patient should have ECoGs stored in the PDMS from which to select specific patterns for detection. Detection settings consist of the ECoG patterns defined and saved as part of a programming set. A pattern defines the type of ECoG activity to be detected. You can define up to four patterns to detect, two patterns on each of two channels. The patterns defined on a specific channel can operate only in that selected ECoG channel. Follow these steps to define a pattern detection set.

1. Using the PDMS on a browser, go to the **PATIENT LIST** and select the patient whose detection settings you will define or change. The **PDMS HOME** screen opens.

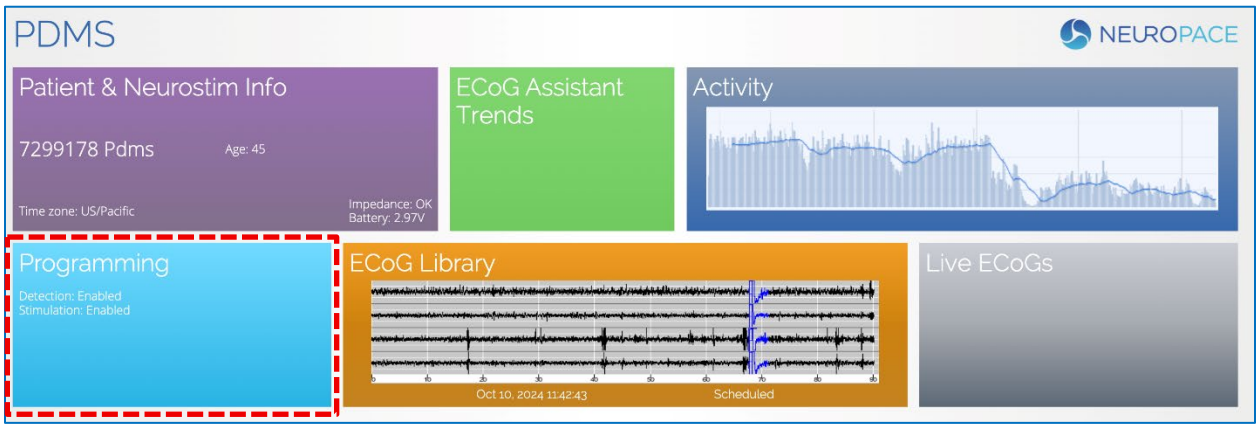


Figure 53 PDMS Home screen

2. Select **PROGRAMMING** from the **PDMS HOME** screen. The **PROGRAMMING** screen opens. On the **PROGRAMMING** screen, select **CHANGE DETECTION** at upper center. The **CHANGE DETECTION** screen opens.

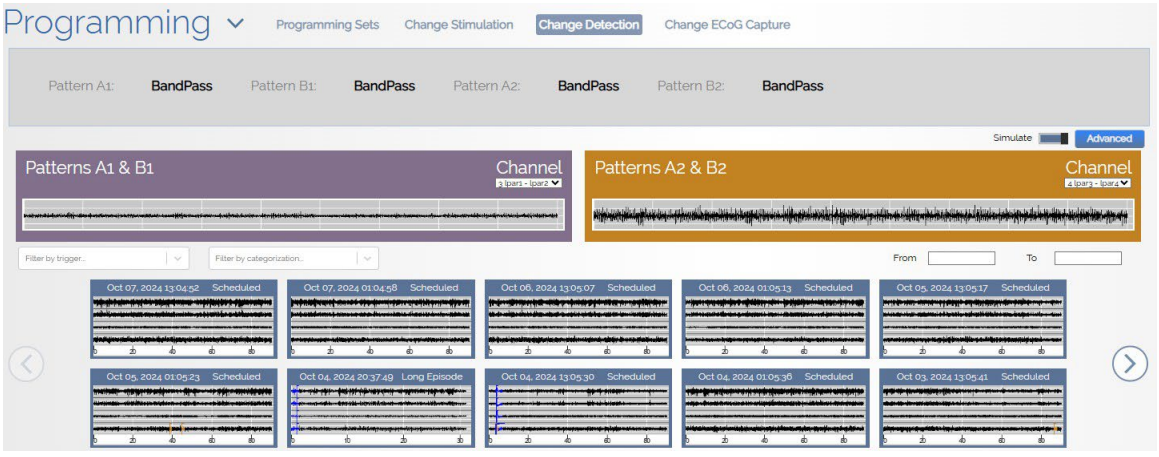


Figure 54 Change Detection screen

- The upper half of the screen provides tiles to select the current detection patterns and channels; the tiles are named **PATTERNS A1 & B1** (upper left) and **PATTERNS A2 & B2** (upper right).
- The lower half of the screen shows thumbnails of all ECoGs (if no filters are on) stored in the PDMS that were captured using the current recording montage. (ECoGs stored in the PDMS were uploaded after interrogations from the remote monitor or programmer.) You can filter the ECoGs shown using the **TRIGGERS** and **CATEGORIES** menus at left center, and by date range using the **FROM** and **TO** fields at middle right.
- The **SIMULATE** button at upper right (next to **ADVANCED**) is switched **ON** (blue) by default, which enables simulations of detections to be shown on all ECoGs shown on this screen.

3. Use the **DEFINE PATTERNS** dialog to define or modify detection settings. There are two routes to the **DEFINE PATTERNS** dialog.
   - Select one of the two **PATTERN** tiles, **PATTERNS A1 & B1** or **PATTERNS A2 & B2**, to go there directly, or
   - Select one of the ECoG thumbnails at the bottom to open its ECoG dialog, which is named by its date and trigger type, and then select one of the two **MODIFY** buttons (**A1 & A2, B1 & B2**) at upper right. (You can also use the ECoG dialog to assign the ECoG to a category if desired.)

If You Selected a New ECoG First

4. If you selected a new ECoG first and selected a **MODIFY** button, a **SELECT CHANNEL** dialog opens. Touch within the channel that has a pattern to detect. Then the **DEFINE PATTERNS** dialog opens.

Using the Define Patterns Dialog

Note: *A pattern defines the type of ECoG activity to be detected.*

5. In the **DEFINE PATTERNS** dialog, the upper portion shows the ECoG in the selected channel. Touch on the point of the ECoG where you would like detection to occur. Starting from the point where you touch, a 3-second window of time (or region of interest, ROI) is bracketed on the ECoG. This touch feature to bracket a 3-second region of interest is called the SimpleStart Feature.

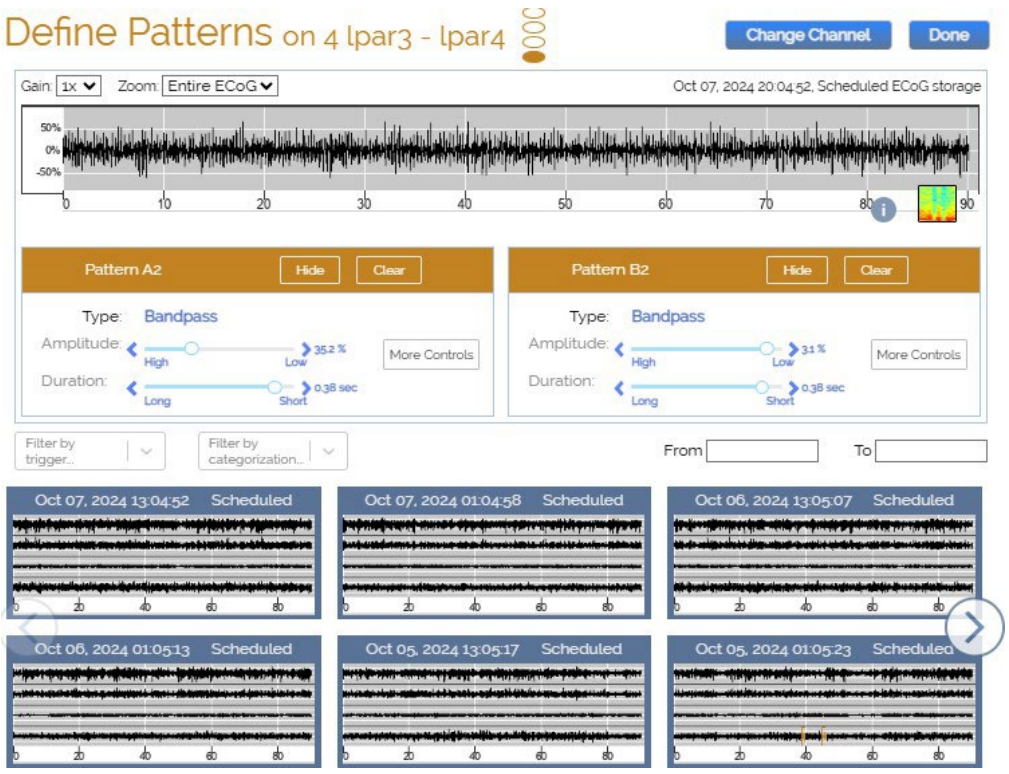


Figure 55 Define Patterns dialog

- The 3-second window bracketed on the ECoG is the pattern you are identifying for detection; it should contain the type of pattern you would like to detect.
- Each 3-second window is identified as one of the four possible patterns you can define, **A1, A2, B1** or **B2**. (The 1 and 2 indicate the first and second ROI you select. Typically, the A and B patterns are defined on different leads.)
- You can touch on the window identifier (**A1, A2, B1** or **B2**) and slide the window left or right to place it where it gives the desired simulated detection results. Note that the software may apply a different suggested detection tool when you move the window.

Note: *You cannot select a 3-second window within the first 5 seconds of an ECOG, because the software looks for differences in the ECOG data before the 3-second window and needs sufficient preceding data to determine this difference. If you touch before 5 seconds in the ECoG, the software places the window starting at the 5-second mark.*

- Normally you want to touch near the beginning of the pattern in order to define a pattern that will be detected promptly after it begins. Detection settings should promptly detect ECoG activity and not detect on baseline activity.

The software automatically applies a suggested detector (shown next to **TYPE**) and settings that fit the waveform pattern in that 3-second window (or region of interest, ROI), and simulates detection, showing the detection flags the chosen pattern would apply to this ECoG—and to all the patient's other stored ECoGs shown in smaller size below. It is recommended to review simulated detection activity on an ensemble of stored ECoGs before finalizing the detection settings.

- To hide the simulation on the ECoG, select **HIDE**. To remove the selection on the ECoG, select **CLEAR**.
- At any point, you can select a different ECoG by selecting an ECoG thumbnail along the bottom; scroll left or right to view all available thumbnails.
- By default, if you define both patterns, detections will occur for both patterns on this channel. The channel is indicated by the filled oval at top center of the dialog, from 1 to 4 top to bottom. Use the **CHANGE CHANNEL** button to change the channel on which to detect the pattern.

Note: *If simulating performance of 2-channel detection settings, be sure to select ECoGs that contain ECoG activity patterns you wish to detect in both channels.*

- Adjust the parameters applicable to the detection tool using the sliders available and observe the effects on the simulation. For **SPIKE ACTIVITY** and **RHYTHMIC ACTIVITY**, the sliders adjust **AMPLITUDE** (%) and **DURATION** (seconds). For **LINE LENGTH**, the sliders adjust **SENSITIVITY** (%) and **DETECT** (seconds).
  - All these detection parameters affect sensitivity. Adjustments that increase sensitivity tend to increase how early and how often the pattern is detected; adjustments that decrease sensitivity tend to decrease how early and how often the pattern is detected.
  - Detection settings should be programmed for early detection of activity. Detection settings that result in early activity detection usually also result in numerous detections; this is expected and acceptable behavior.
  - The parameter values are shown to the right of each slider. For all four parameters, lower values result in greater sensitivity.
  - The **MORE CONTROLS** button gives access to additional controls.

6. Select **DONE** at upper right to close the **DEFINE PATTERNS** dialog. You return to the **CHANGE DETECTION** screen.
7. For next steps, see *Create a Programming Set* on page *35*.

PHASE 3: CUSTOMIZE DETECTION

To customize pattern detection is to refine detection settings to promptly detect the specific patterns for this patient, and not detect on baseline activity, since detection serves as the basis for neurostimulator treatment. On visits subsequent to *Phase 2: Define Detection Settings* on page *54*, the usual, systematic approach is to make small, incremental adjustments to individual parameters of a detection pattern. The adjustment you make may be intended to increase or decrease how early and how often the pattern is detected, based on your assessment of current detection activity as viewed on stored ECoGs and on the **ACTIVITY** screen.

Note: *Typically, physicians repeat earlier phases (Phase 1 or Phase 2) only if they observe a new type of ECoG activity of interest that requires an additional detector; or if a good clinical response has not been obtained and they wish to start over.*

Recommended: Change and Simulate Detection Settings Before Patient Visit on the PDMS

To have full control of detection settings, it is recommended that clinicians prepare detection settings (as part of a programming set) before a patient's follow-up visit. In this way, the clinician can review the proposed detection changes through simulated detection on the patient's previously saved ECoGs. To do this, you must use the PDMS via web browser on a personal computer.

1. Using the PDMS on a browser, go to the **PATIENT LIST** and select the patient whose detection settings you will define or change. The **PDMS HOME** screen opens.

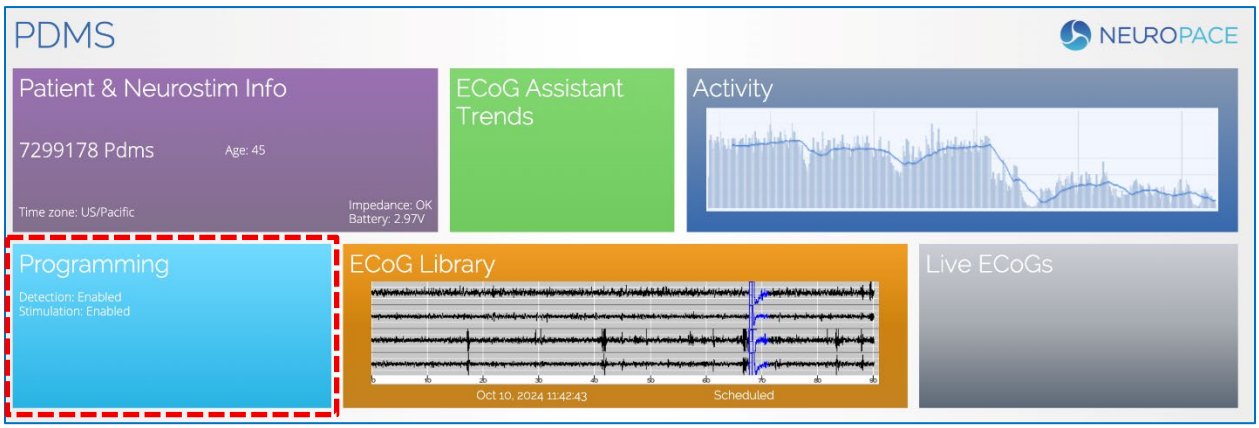


Figure 56 PDMS Home screen

2. Select **PROGRAMMING** from the **PDMS HOME** screen. The **PROGRAMMING** screen opens. On the **PROGRAMMING** screen, select **CHANGE DETECTION** at upper center. The **CHANGE DETECTION** screen opens.

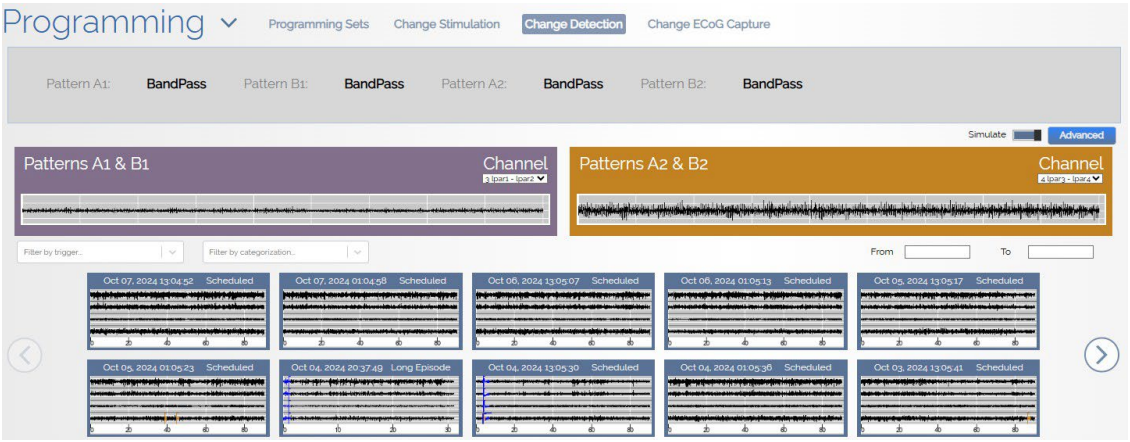


Figure 57 Change Detection screen on the PDMS (outside an interactive programming session)

The upper half of the screen provides tiles to select the current detection patterns and channels; the tiles are named **PATTERNS A1 & B1** (upper left) and **PATTERNS A2 & B2** (upper right).

- The lower half of the screen shows thumbnails of all ECoGs (if no filters are on) stored in the PDMS that were captured using the current recording montage. You can filter the ECoGs shown using the **TRIGGERS** and **CATEGORIES** menus at left center.
- The **SIMULATE** button at upper right (next to **ADVANCED**) is switched **ON** (blue) by default, which enables simulations of detections to be shown on all ECoGs shown on this screen.

3. Select one of the two **PATTERN** tiles at the top to access the **DEFINE PATTERNS** dialog.

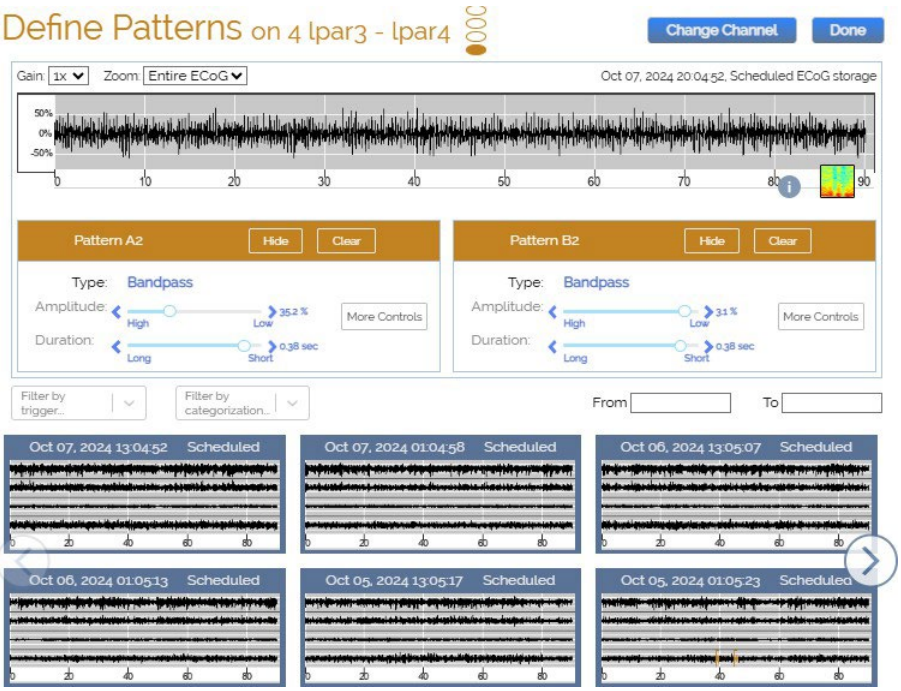


Figure 58 Define Patterns dialog

4. In the **DEFINE PATTERNS** dialog, select and adjust the desired parameter using the sliders so as to increase or decrease how early and how often the pattern is detected.

The software automatically simulates detection with the changed parameter as applied to this ECoG and to the patient's other stored ECoGs shown in smaller size below. It is recommended to review simulated detection activity on an ensemble of stored ECoGs before finalizing your adjustment.

- If necessary, scroll to view the bottom of the dialog where the ECoGs appear with simulated detection; use the right arrow or left arrow button to see more ECoGs if available. You can filter the ECoGs using the **TRIGGERS** and **CATEGORIES** menus, and/or the **FROM** and **TO** date range fields.
- To hide the simulation on the ECoG, select **HIDE**. To remove the pattern on the ECoG, select **CLEAR**.
- Detection parameters that affect sensitivity are key: adjustments that increase sensitivity tend to increase how early and how often the pattern is detected; adjustments that decrease sensitivity tend to decrease how early and how often the pattern is detected.
- To adjust sensitivity, the two most common parameters to adjust are the ones with sliders directly on the **DEFINE PATTERNS** dialog. For **SPIKE ACTIVITY** and **RHYTHMIC ACTIVITY**, the sliders adjust **AMPLITUDE** (%) and **DURATION** (seconds). For **LINE LENGTH**, the sliders adjust **SENSITIVITY** (%) and **DETECT** (seconds).

Note: *The parameter values are shown to the right of each slider. For all four parameters, lower values result in greater sensitivity. Make adjustments and observe the effects on the simulation.*

Advanced Settings for Detection on the PDMS

- Select **MORE CONTROLS > ADV SETTINGS** to open the **ADVANCED SETTINGS** dialog for the pattern you are currently defining, which gives access to additional settings for the detection tools **BANDPASS**, **LINE LENGTH** and **AREA**. (**AREA** can be selected only in this dialog.) Select the down-arrow next to **TECHNICAL PARAMETERS** to access even more settings. You can select more than one tool for use at the same time in this dialog.

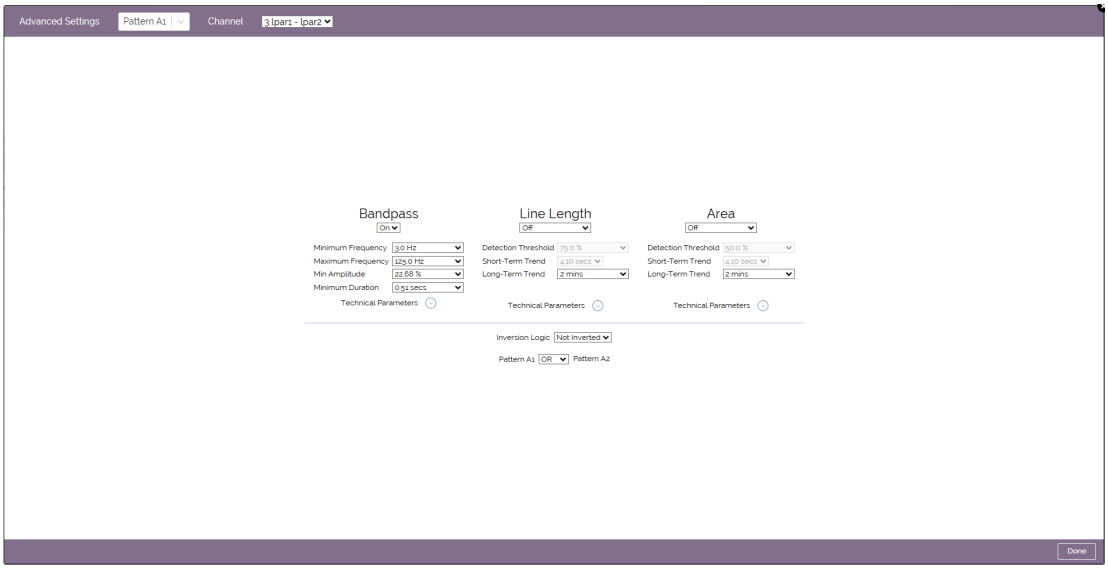


Figure 59 Advanced Settings dialog on the PDMS (outside interactive programming)

- Select **DONE** at bottom or the circle-X (exit) button at upper right to close the **ADVANCED SETTINGS** dialog. You return to the **DEFINE PATTERNS** dialog.

5. When finished making changes in the **DEFINE PATTERNS** dialog, select **DONE** at upper right to close it.
6. Follow the instructions to *Create a Programming Set* on page *35*.

CHANGE DETECTION DURING INTERACTIVE PROGRAMMING ON THE PROGRAMMER

Note: *During an interactive programming session, the **CHANGE DETECTION** screen allows you to change advanced settings only. This means you cannot use the ECoG Assistant functionality, nor select an epileptiform pattern to detect from a patient's saved ECoGs, nor simulate detection on all the patient's saved ECoGs.*

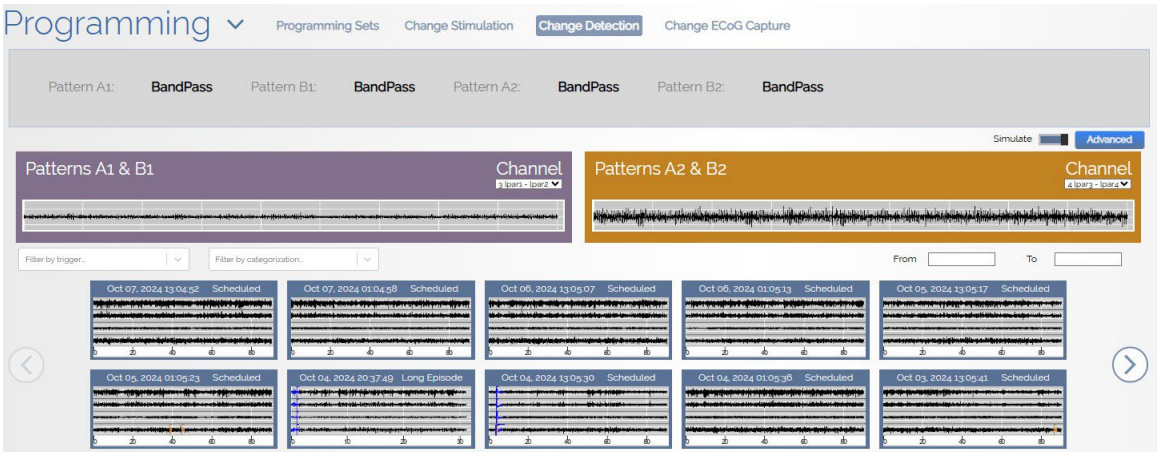


Figure 60 CHANGE DETECTION screen during interactive programming on the programmer

- Select **ECOG CHANNEL FOR PATTERNS A1 & B1**, or ECoG Channel for Patterns A2 & B2, to select a different channel for those patterns or to turn the channel off.
- To access advanced settings that you can change manually for each pattern, select one of the four colored tiles to **MODIFY PATTERN A1, B1, A2**, or **B2**. This opens the **ADVANCED SETTINGS** dialog, which gives access to additional settings for the detection tools **BANDPASS, LINE LENGTH** and **AREA**. (**AREA** can be selected only in this dialog.) Select the down-arrow next to **TECHNICAL PARAMETERS** to access even more settings. You can select more than one tool for use at the same time in this dialog.

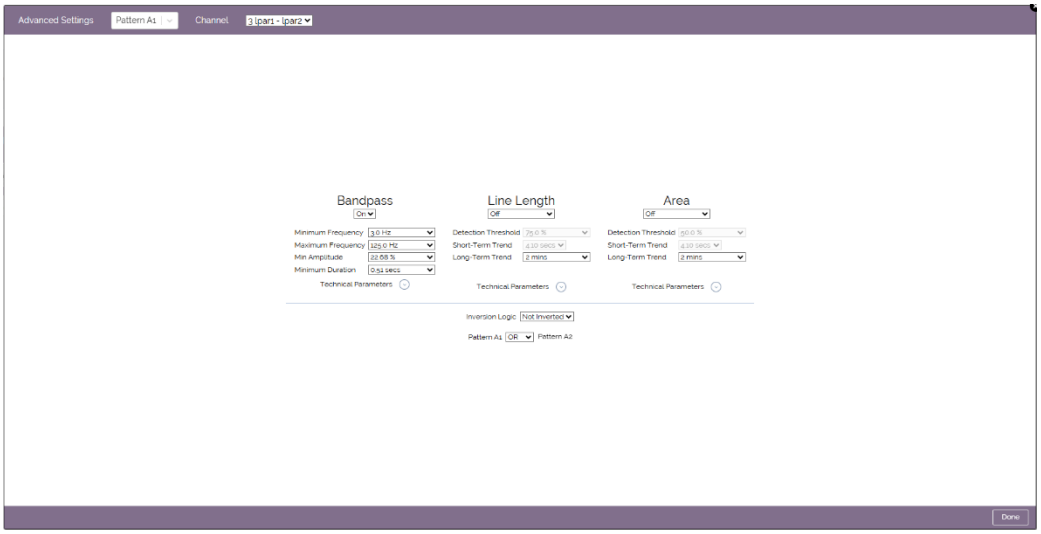


Figure 61 Advanced Settings dialog during interactive programming

- Select **DONE** at lower right to close the dialog when finished making changes. Your changes will be retained back in the **PROGRAMMING SETS** screen, where you can review the **PENDING PROGRAMMING CHANGES**. If satisfied, select **PROGRAM RNS** to program the resulting programming set, automatically named "Clinic Set" with date and time, into the neurostimulator. The Clinic Set will be saved on the PDMS when the programmer is connected to the Internet.

CONFIGURE RESPONSIVE THERAPY

Detection must be enabled before responsive therapy can be enabled. Before programming responsive therapy, at least one detector must be defined in a detection set. (If you select therapy specific to a detection pattern, at least one detector must be defined for each pattern.) To set up a therapy sequence, determine the number of therapies desired for delivery in response to an episode. Select each therapy and configure each burst, which is a collection of one to many biphasic pulses. See details in *Overview of Responsive Therapy* on page *46*.

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.*

Note: *It is recommended to review and perform detection analysis prior to enabling responsive therapy.*

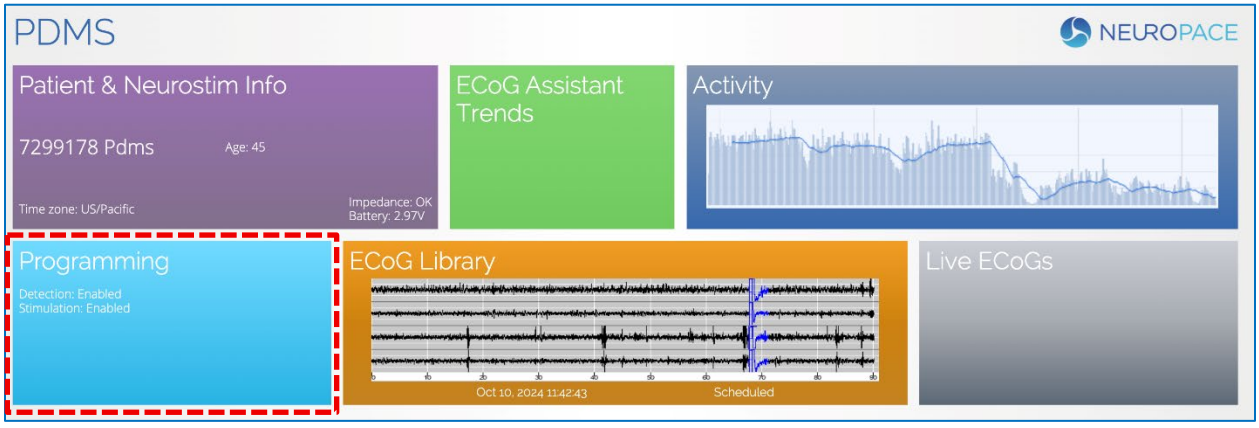


Figure 62 Select Programming tile on Home screen

1. Select **PROGRAMMING** from the PDMS **HOME** screen.
2. Select **CHANGE STIMULATION** at upper center of the **PROGRAMMING** screen. The **CHANGE STIMULATION** screen opens.

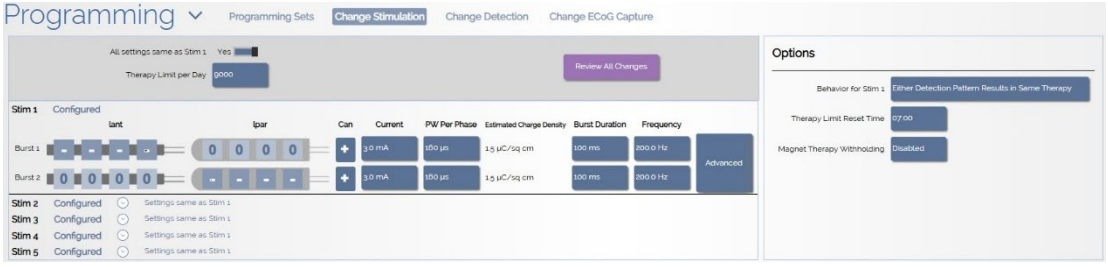


Figure 63 Change Stimulation screen

The screen has rows **STIM 1** through **STIM 5** to program up to five stimulation therapies. Each therapy is either configured or disabled. When one of the five therapies is disabled, all successive therapies are disabled also—you cannot skip a therapy. Recall that detection must be enabled before any therapy can be configured.

3. **Select Stimulation Pathway:** The stimulation pathway consists of the electrodes and Can across which stimulation is delivered, as configured by the user. For each desired Stim Burst, starting with **STIM 1 BURST 1**, select the electrodes including the Can across which to deliver therapy, by making at least one electrode positive **[+]** and another negative **[–]**.

   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.

4. Select the level of **CURRENT** to be delivered during pulses.

5. Select the **PW PER PHASE**, which is the pulse width or duration (in µs) of each phase of the biphasic current pulse.

   Note: *The **ESTIMATED CHARGE DENSITY** calculation combines **CURRENT** and **PW PER PHASE** values with the area of the smaller electrode (Anode or Cathode), whichever has less surface area. The programmer limits the available choices for **CURRENT** and **PW PER PHASE** to those which yield an **ESTIMATED CHARGE DENSITY** less than 25 µC/sq cm.*

6. Select the **BURST DURATION**, from 10 ms to 5000 ms.

7. Select the **FREQUENCY** of the biphasic current pulses, from 1 Hz to 333.3 Hz. Increasing frequency decreases the time between each biphasic pulse of current.

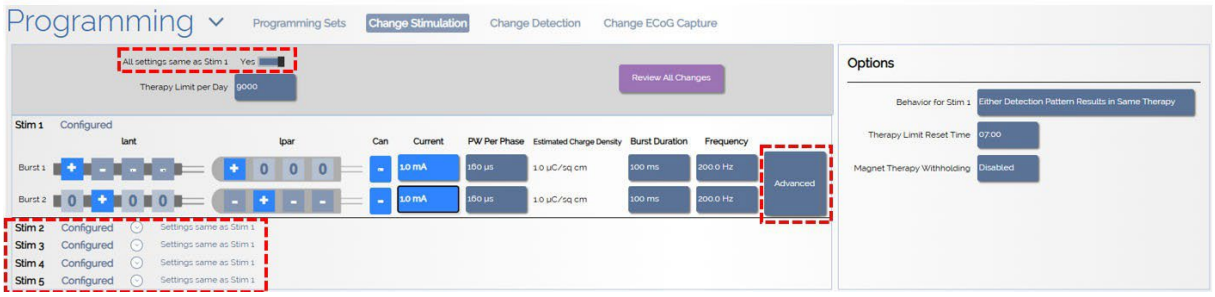


Figure 64 Stim 1 settings copied to all therapies

8. To apply the same settings to all five stimulation therapies, make sure the button next to **ALL SETTINGS SAME AS STIM 1** is toggled to **YES**, near top left of the screen. To make different settings for Stim 2 or higher, select the **YES** button to toggle it to **NO** and then make changes.

   - Note that the **REVIEW ALL CHANGES** button appears when you begin to edit settings.

9. If desired, select **THERAPY LIMIT PER DAY** at upper left to adjust the maximum number of episodes the neurostimulator will treat per day.

10. If desired, scroll left to access the **OPTIONS** area on the right side of the **CHANGE STIMULATION** screen to find the following options:

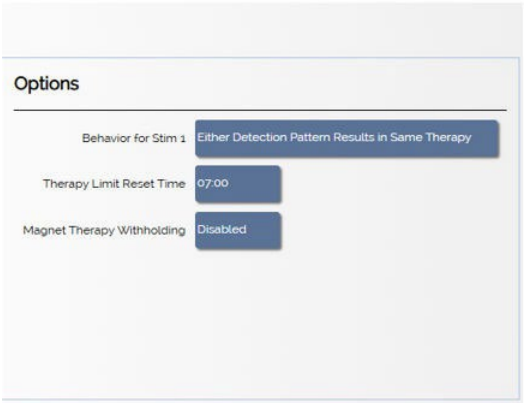


Figure 65 Options on the right side of the Stimulation settings screen

- **BEHAVIOR FOR STIM 1:** The default is Either Detection Pattern Results in Same Therapy. Select the field to select the alternate **DETECTION PATTERN SPECIFIC THERAPY**, to apply only Therapy 1 in response to detection of one specific pattern you have programmed.
- **THERAPY LIMIT RESET TIME:** Select the time of day (in 24-hour time) when the daily therapy limit count resets to zero.
- **MAGNET THERAPY WITHHOLDING:** The default is **ENABLED**, which enables the magnet to withhold therapy as long as the magnet is over the neurostimulator. Once the magnet is removed, therapy can resume. To disable this functionality, select the field to toggle to **DISABLED**.

Scroll right to return to the left side of the **CHANGE STIMULATION** screen.

- If desired, select **ADVANCED** at far right of the row to adjust the *Optional Advanced Settings* on page *65*.

11. Skip to *Test Stimulation Before Programming* on page *87* if you do not want to use the advanced settings.

OPTIONAL ADVANCED SETTINGS

If desired, select **ADVANCED** at far right of the row to open the **ADVANCED SETTINGS** screen for the selected therapy (**STIM** row). By default, all advanced settings are disabled.

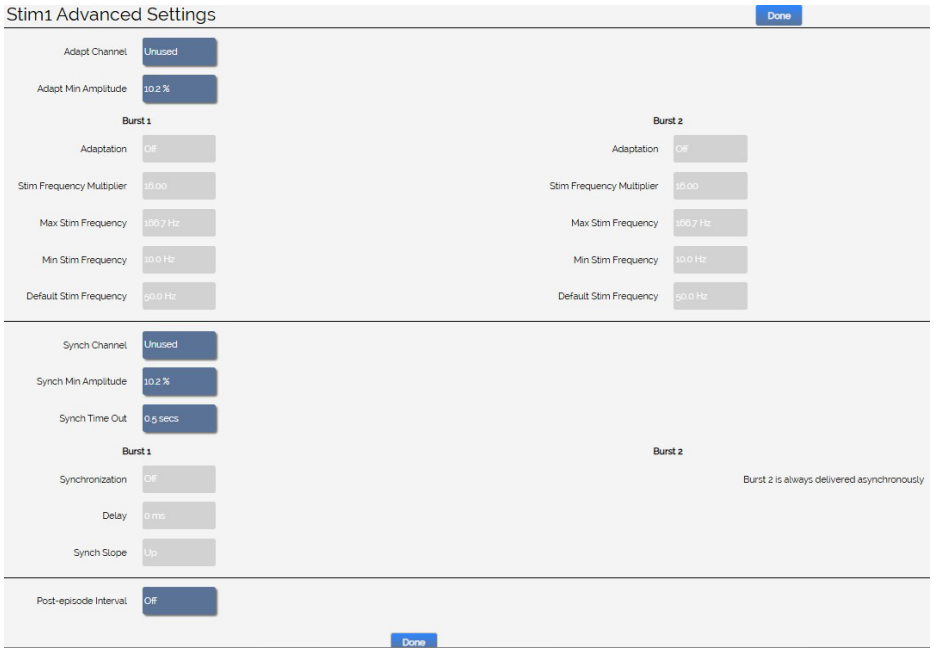


Figure 66 Stim 1 Advanced Settings

The **ADVANCED SETTINGS** screen has upper, lower and bottom portions that let you select the following:

Upper portion—Adaptive Therapy: Adapts the frequency of the stimulation therapy as a percentage of the detected signal amplitude over a chosen channel, for one or both bursts. The available options are:

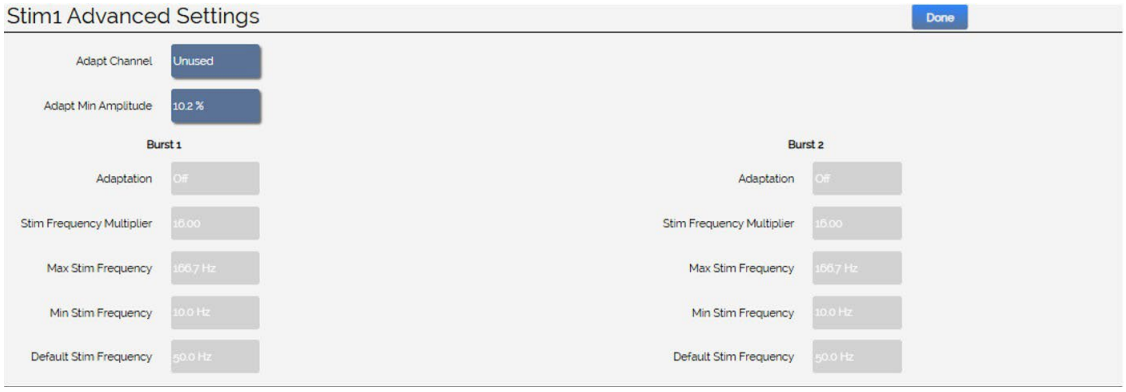


Figure 67 Adaptive therapy settings—upper portion of Advanced Settings dialog

- **ADAPT CHANNEL**: Select one of four channels over which to enable adaptive therapy. By default, this is **UNUSED**, which means adaptive therapy is disabled.

- **ADAPT MIN AMPLITUDE**: Select a percentage of the detected signal amplitude to be used as the minimum therapy amplitude.

Then for **BURST 1** and/or **BURST 2**, select settings for the following:

- **ADAPTATION**: Turn **ON** or **OFF** adaptive therapy for this burst.
- **THERAPY FREQUENCY MULTIPLIER**: A greater multiplier increases frequency of the burst.
- **MAX THERAPY FREQUENCY**: Sets maximum frequency for this burst.
- **MIN THERAPY FREQUENCY**: Sets minimum frequency for this burst.
- **DEFAULT THERAPY FREQUENCY**: Sets default frequency for this burst.

Illustration: If **ADAPT MIN AMPLITUDE** = 100% and the detected signal frequency = 20 Hz (50 ms period), the stimulation frequency is delivered at 20 Hz (50 ms p-p interval). If **ADAPT MIN AMPLITUDE** = 50% and the sensed signal frequency = 20 Hz (50 ms period), the stimulation frequency is delivered at 40 Hz (25 ms p-p interval).

If the neurostimulator cannot detect a stable frequency in the ECoG signal, or if the calculated stimulation frequency is not between the **MAX THERAPY FREQUENCY** and **MIN THERAPY FREQUENCY**, then the burst is delivered at the **DEFAULT THERAPY FREQUENCY**.

Lower portion—Synchronized Therapy: For **BURST 1** only, synchronize delivery of therapy into a specific part of the detected ECoG waveform over a chosen channel. The available options are:

Figure 68 Synchronized therapy settings—lower portion of Advanced Settings dialog

- **SYNCH CHANNEL**: Select one of four channels over which to deliver synchronized therapy.
- **SYNCH MIN AMPLITUDE**: Select a percentage of the detected signal amplitude to be used as the minimum amplitude for synchronized therapy.

Then for **BURST 1** and/or **BURST 2**, select settings for the following:

- **SYNCHRONIZATION**: Turn **ON** or **OFF** synchronized therapy for **BURST 1**. (**BURST 2** is always delivered asynchronously.)
- **DELAY**: Set the delay (in ms) for delivery of **BURST 1** therapy after detection of the target ECoG waveform.
- **SYNCH SLOPE:** Select Up or Down.

Note: *If the neurostimulator is unable to synchronize therapy into a detected waveform, it reverts to asynchronous therapy delivery after 2 seconds.*

Bottom portion—Post-Episode Interval: Select the **POST-EPISODE INTERVAL**, from **OFF** (default) to **24 HRS**, to specify the time the neurostimulator waits after the end of an episode before treating a new episode. During the post-episode interval, monitoring continues but the system will not deliver therapy for a new episode.

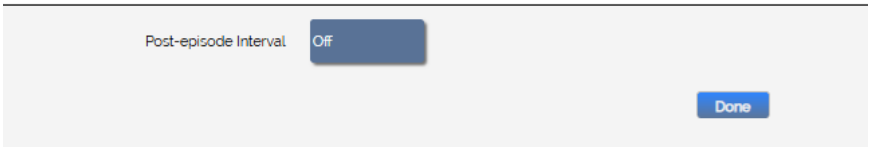


Figure 69 Post-episode interval settings—bottom portion of Advanced Settings dialog

Save Advanced Settings: Select **DONE** to save the new advanced settings and return to the **CHANGE STIMULATION** screen. As usual while using the PDMS, you must select **REVIEW ALL CHANGES**, then **SAVE** the programming set and share it with programmers. To test stimulation, you must use the Programmer with Wand and the patient present.

RECOMMENDED INITIAL RESPONSIVE THERAPY SETTINGS

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

- Program **BURST 1** for electrodes on one lead and **BURST 2** for electrodes on the other lead
- **FREQUENCY** = 200 Hz (default)
- **BURST DURATION** = 100 ms (default)
- **PW PER PHASE** = 160 µs (default)
- **CURRENT** = 1.0 mA
- The RNS Programmer estimates charge density based on current, PW per phase, and the number of electrodes in the stimulation pathway. After selecting PW per phase and stimulation pathway, the physician should adjust current to achieve targeted charge density. For example, for a stimulation pathway with all electrodes on one lead programmed cathodal and the Can programmed anodal, using the default PW per phase value of 160 µs and setting current to 1.0 mA results in charge density of 0.5 µC/sq cm.
- Apply the same settings to all five stimulation therapies: select the **YES** button next to **ALL SETTINGS SAME AS STIM 1**, near top center of the screen.

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.

Recommended Therapy Modifications After Observing Clinical Response

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 programmer. Detection settings should promptly detect ECoG activity and not detect on baseline activity.

Based on the clinical response, the physician may choose to modify stimulation. After selecting PW per phase and stimulation pathway, current can be used to adjust charge density. It is recommended that the charge density be increased in 0.5 µC/sq cm increments. Longer pulse widths or fewer electrodes result in larger charge density changes for each mA current change. It is strongly recommended that the new settings be tested (see *Test Stimulation Before Programming* on page *87*) to ensure that it is well tolerated by the patient and there are no undesired changes in the ECoG such as afterdischarges.

- Review data such as lead impedance, battery voltage, number of detections and stimulations, and stored ECoGs.
- Adjust stimulation settings if the patient reports an acute worsening or increase in clinical seizures that is not typical.
- Consider making minor adjustments if the patient reports only a mild or no improvement in clinical seizures.
- Allow sufficient time between stimulation adjustments to assess the patient's clinical seizure response.

In the RNS System Pivotal study very few subjects used any of the additional responsive stimulation therapy options (see *Table 3* below). These were: pattern specific therapy (each detector triggers a different stimulation setting); adaptive therapy (the stimulation frequency adjusts with the ECoG frequency); synchronized stimulation (stimulation is delivered into a specific part of the ECoG waveform); and post episode interval (responsive therapies are disabled for a specified period of time after detecting the end of the episode). *Table 3* below provides the number and percentage of subjects who were treated with any of the additional stimulation therapy options.

Table 3 Additional responsive stimulation therapy options

Stimulation Therapy Options	Number and (%) of Subjects Programmed
Pattern Specific Therapy	29 (15%)
Adaptive Therapy	4 (2%)
Synchronized Stimulation	3 (2%)
Post-Episode Interval	4 (2%)

Making a Programming Set Available for Programming

Programming sets created on the PDMS are saved to the PDMS only. You must actively share any programming set saved on the PDMS to make it available to anyone for programming, including yourself. To share a programming set, see instructions under Share a Programming Set on page *36*.

> ***Note:*** *To access shared programming sets on the programmer, the programmer must be connected to the Internet during programming. If not connected to the Internet, only default programming sets and programming sets previously downloaded to the programmer are available for programming. You can modify any available programming set before programming the RNS. To connect to the Internet, see* *Power On the Programmer on page 70.*

Note: *If a clinic environment lacks Internet connectivity, shared programming sets are not accessible during an interactive session. Before bringing the programmer into the clinic, it is necessary to download the programming set from the Patient List to the programmer; the downloaded programming set will be available when the programmer is offline during the interactive session. Follow the* *Steps to Download a Programming Set to the Programmer for Offline Use* *on page* *90*.

Any programming set that is available on the programmer during an interactive session can be modified before programming the RNS Neurostimulator.

USING THE RNS PROGRAMMER

RNS PROGRAMMER SETUP AND LOGIN

OVERVIEW

This section of the manual primarily addresses use of the programmer during an interactive programming session, that is, when the clinician uses the wand for communication between the RNS Neurostimulator and RNS Programmer.

The PDMS patient database is integrated with the RNS Programmer; but PDMS functionality is maximized by accessing to the PDMS using a browser on any internet-connected computer rather than connecting through the programmer. The programmer ships with mobile broadband enabled and Wi-Fi disabled. The RNS Programmer can detect available Wi-Fi networks out of the box and instructions to connect to Wi-Fi are provided within this manual When connected to the internet and logged in to the PDMS, the RNS Programmer provides a look- through to the information stored on the PDMS Application software, such as ECoGs, neurostimulator settings and activity.

> ***Note:*** *Attempting to connect to a Wi-Fi network that requires the use of an internet website to log in, as in some hotels and coffee shops, will result in an inability to log in because the RNS Programmer does not have an Internet browser program. As a medical device, its Internet connectivity is restricted.*

The section explains *RNS Programmer Functionality with and without an Internet Connection* on page *75* and provides instructions to *Power On the Programmer* on page *70* and *Log In to the PDMS on the RNS Programmer* on page *75*.

POWER ON THE PROGRAMMER

Make sure the programmer is sufficiently charged for use before powering on. When interacting with a patient, the programmer should be used on battery power only. Press and hold the power button on the upper right side of the programmer. After 2-3 seconds, activity begins on screen, which indicates it is powering on.

Access to all the functionality of the RNS Programmer, including PDMS, requires internet access, and two logins (one log in to the RNS Programmer and one log in to the PDMS).

1. Connect to the Internet

Use Wi-Fi or mobile broadband to connect the programmer to the internet. To connect to Wi-Fi, follow the steps below. Mobile broadband is pre-configured by NeuroPace to be on and working, so no further effort is necessary, and the programmer will connect to mobile broadband automatically if a signal is available.

Touch to select the small symbol that indicates network status, as indicated below. If necessary, touch outside the login fields to dismiss the keyboard and see the whole screen. The Wi-Fi symbol indicates an available Wi-Fi network.

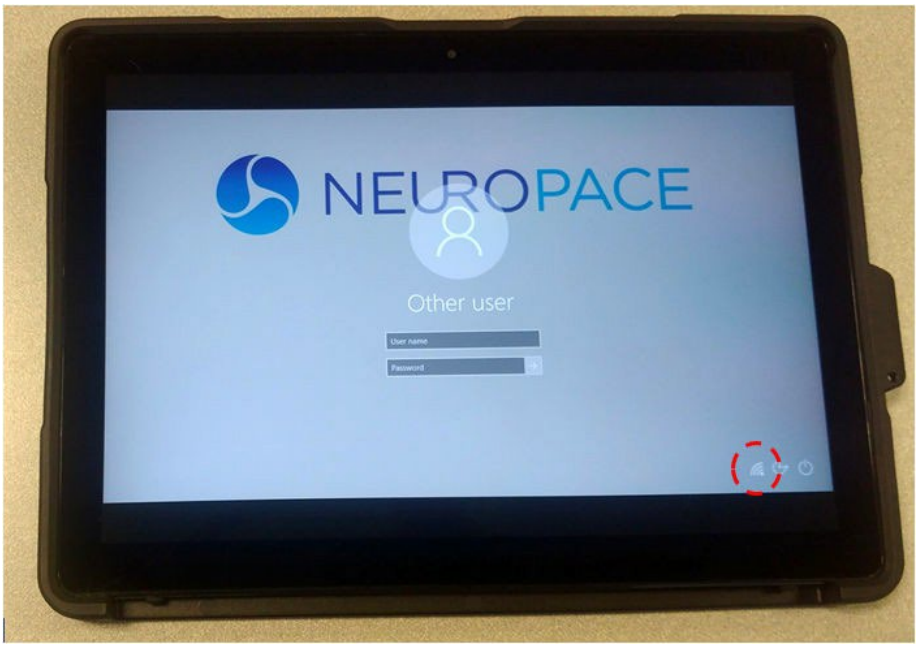


Figure 70 Touching the Wi-Fi network icon at lower right

Selecting the Wi-Fi symbol opens the **NETWORKS** panel. Wi-Fi access is the same as on a personal/ laptop computer or smartphone.

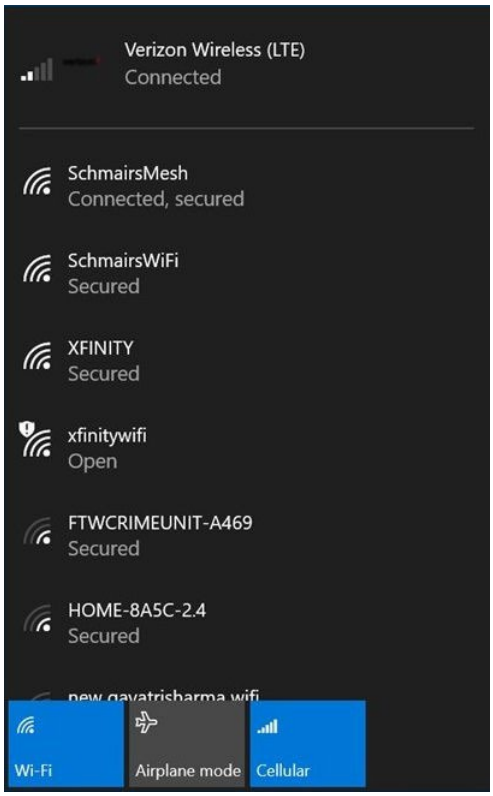


Figure 71 Networks panel

Select the desired network and then select **CONNECT**. Enter the network security key and select **NEXT**.

Note: *The security key is your Wi-Fi password. The programmer connects if the security key is correct. Internet connection is complete.*

LOSS OF NETWORK CONNECTIVITY

If network connectivity is lost, wait for the signal to be restored or you can exit the programmer and try to connect to a Wi-Fi network. To do this, first log off to return to the programmer login screen: return to the Start screen and touch the circle X (exit) button at upper right, and then select **EXIT** on the **PROGRAMMER EXIT** dialog.

2. Log In to the RNS Programmer

Access to the secure RNS Programmer requires a username and password. If NeuroPace has not provided these to you, contact NeuroPace to obtain a username and password (see *Contact NeuroPace* on back page). You are responsible for maintaining the confidentiality of your username and password.

The log in screen appears first upon startup. Select a user. Enter a username and password (provided by NeuroPace) using the keyboard displayed and select **ENTER**.

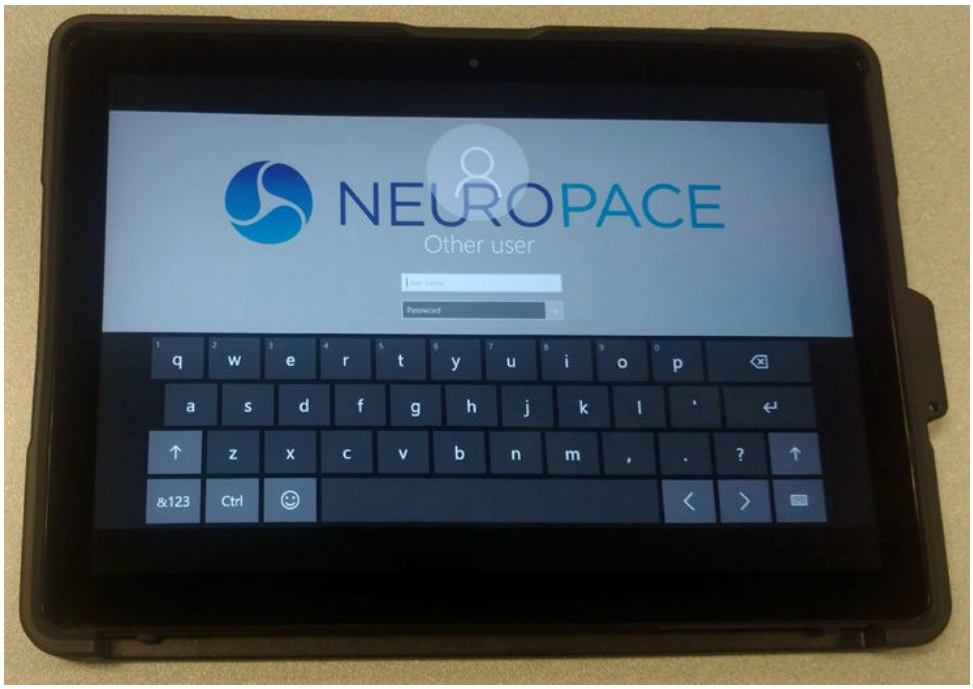


Figure 72 Enter username and password

Log in completes if the password is correct.

> ***Note:*** *If updates are available, the* ***NEUROPACE UPDATE CENTER*** *opens (see NeuroPace Update Center on page 114).*
>
> *If there are no updates, the Start screen appears (see Start Screen on page 74), which lets you either interrogate a patient's neurostimulator to begin an interactive programming session, or select a patient from the* ***PATIENT LIST****, after logging in to the PDMS.*

START SCREEN

The Start screen of the RNS Programmer opens immediately when log in is successful. The Start screen provides access to **INTERROGATE** the RNS Neurostimulator or access the **PATIENT LIST** via the PDMS.

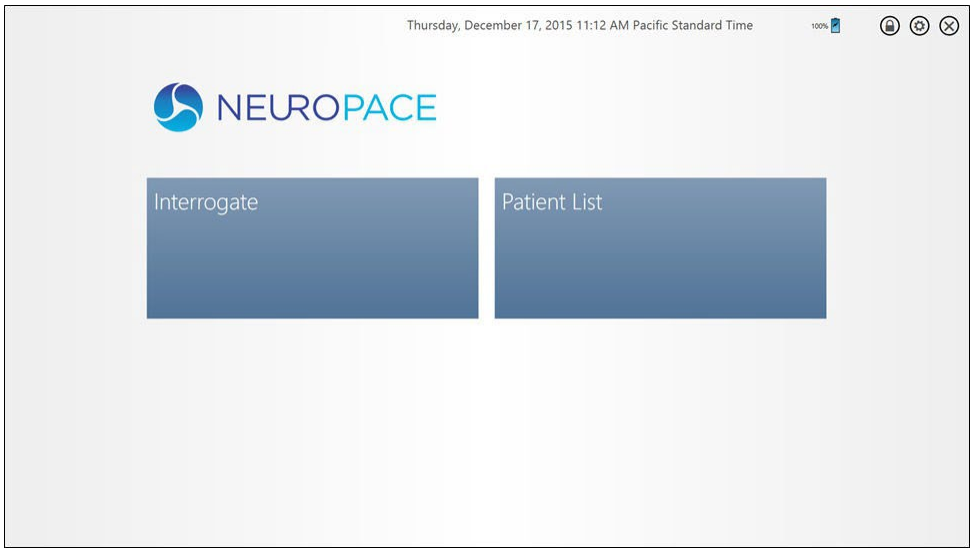


Figure 73 Start screen

INTERROGATE: Select the **INTERROGATE** tile to begin an interactive programming session with a patient present. PDMS login is not required. For instructions to interrogate, see *Interrogate the RNS Neurostimulator* on page *79*.

PATIENT LIST: Select the **PATIENT LIST** tile to access patient information similar to the PDMS on a web browser via a Personal Computer. Apart from screen dimensions, the appearance and behavior on the available PDMS screens are the same as when accessing the PDMS via a web browser, except for the unavailability of the AI-Powered **ECoG Assistant** functionality and **ECOG ASSISTANT TRENDS** report. Selecting the **PATIENT LIST** tile directs the clinician to the PDMS log in screen. The clinician will be prompted to *Log In to the PDMS on the RNS Programmer* on page *75*.

DOWNLOAD A PROGRAMMING SET FOR OFFLINE USE

One important scenario to select the **PATIENT LIST** tile is when planning to program a new programming set in a clinic or an operating room that lacks reliable Internet connectivity. The programming set must be downloaded directly from the PDMS to the programmer before the appointment or procedure. For instructions in this scenario, see *Steps to Download a Programming Set to the Programmer for Offline Use* on page *90*.

LOG IN TO THE PDMS ON THE RNS PROGRAMMER

The **PDMS LOG IN** screen appears on the programmer whenever an attempt to access functions that require PDMS access are selected, such as selecting the **PATIENT LIST**, **ECOG LIBRARY** or **ACTIVITY** tiles. Logging in to the PDMS requires the internet connection to be established before logging in to the programmer. NeuroPace provides the initial username and password for the PDMS. If you have forgotten your password, select **RESET YOUR PASSWORD OR ACCESS YOUR PASSWORD HINT**. The password hint you entered will be sent to the email address listed in your PDMS profile.

Select the fields to enter the username and password and then select **LOG IN**.

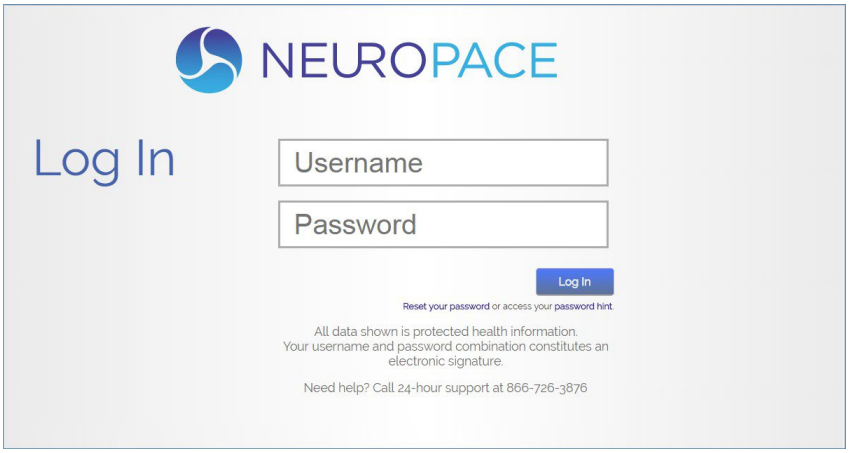


Figure 74 PDMS Log In Screen on the RNS Programmer

RNS PROGRAMMER FUNCTIONALITY WITH AND WITHOUT AN INTERNET CONNECTION

> ***Note:*** *Programming functions that are typically performed in the operating room do not require an Internet connection to the PDMS. Default programming sets are always available on the programmer. Custom programming sets, however, are only available when the programmer is connected to the Internet or they have been downloaded to the programmer. When a patient's custom programming set will be programmed in an environment that lacks Internet connectivity, the custom programming set must be downloaded to the programmer. (See Download a Programming Set on page 90.)*

You can access all programming functions without an Internet connection to the PDMS except the following:

- View patient information stored on the PDMS
- Upload local patient data to the PDMS
- Download programming sets from the PDMS for use offline

Table 4 Functionality with and without an Internet Connection	
Function	**Without Internet Connection to the PDMS**
Interrogate the neurostimulator	Yes
View neurostimulator information and settings downloaded during current session, including ECoGs, battery voltage, impedance, stimulation settings, recording montage	Yes
Create or change the recording montage	Yes
Set up or adjust ECoG capture settings	Yes
Select and program a default programming set or a custom programming set previously downloaded to the programmer from the PDMS	Yes
Make a new programming set or adjust parameters of a programming set	Yes
View patient information stored on the PDMS	No
Upload local patient data from the programmer to the PDMS	No
Access programming sets stored on the PDMS, either to use immediately, or to download for later use offline	No

RNS PROGRAMMER HOME SCREEN

The programmer Home screen is the hub for all programming activities. It is accessed by logging in to the programmer and initiating an interactive programming session. To begin an interactive programming session, select the **INTERROGATE** tile on the **START** screen (see *Start Screen* on page 74) and position the wand to interrogate the neurostimulator (see *Interrogate the RNS Neurostimulator* on page 79). The Home screen appears when the interrogation completes successfully.

The programmer Home screen has six colored tiles, each providing additional data different types of data and functionality when selected.

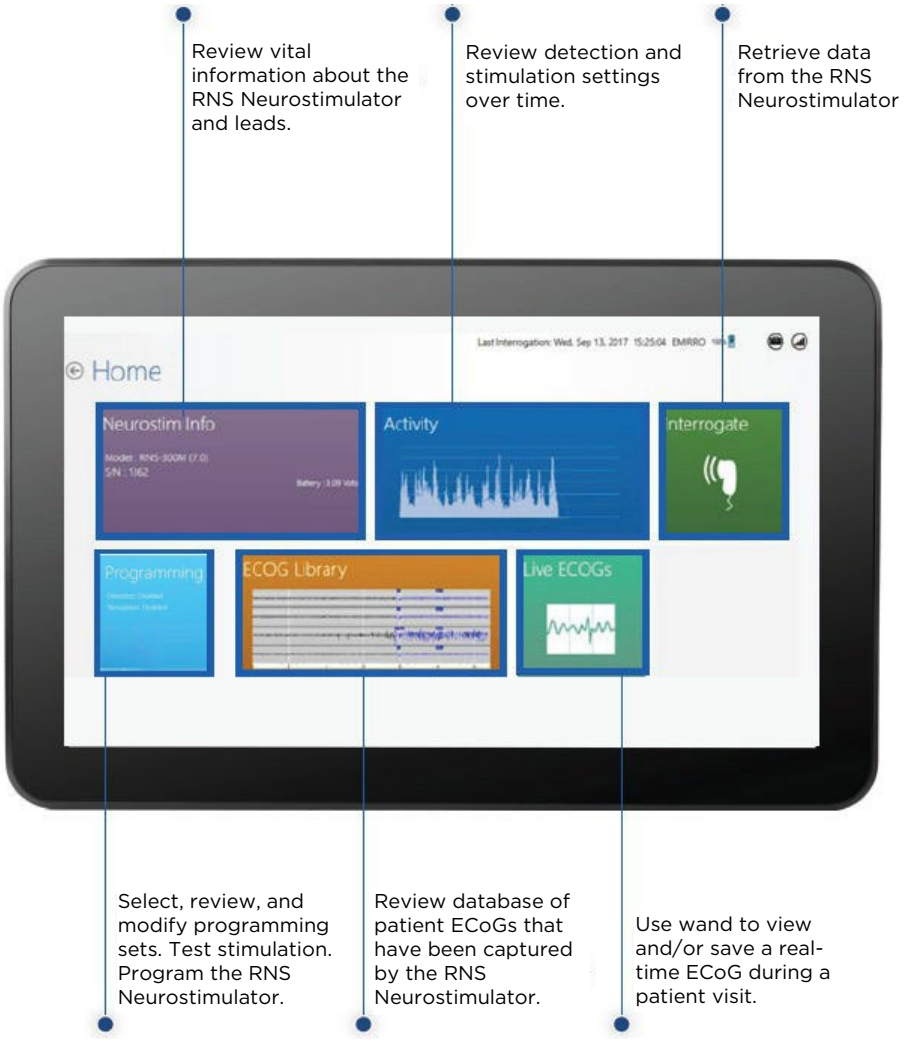


Figure 75 Six Tiles on the Home Screen

The elements in the far upper right of the screen are present on all programmer screens.

- **LAST INTERROGATION** date (YYYY-MM-DD) and time (24-hour time)
- Username (if logged in to the PDMS)
- Programmer battery status (%)

- **TOOLBOX** button to access **UTILITIES** dialog to **IMPORT DEVICE** and **EXPORT DEVICE SETTINGS**. These features are designed to support neurostimulator replacement. For instructions, see *Export and Import Device Settings for Neurostimulator Replacement* on page *102*.
- Wireless Signal button to access the PDMS Communication Log

NEUROSTIM INFO

Select the purple **NEUROSTIM INFO** tile to check basic information about the patient and RNS Neurostimulator status and programmed parameters. For details, see *Review Neurostim Info* on page *81*.

ACTIVITY

Select the dark blue **ACTIVITY** tile to open the **ACTIVITY** screen. The **ACTIVITY** screen enables review of the ECoG capture, and detection and stimulation settings used over time. For details, see *Review Activity* on page *28*.

INTERROGATE

Select the dark green **INTERROGATE** tile, to interrogate the neurostimulator and retrieve any data stored on the neurostimulator since the previous interrogation (e.g., initiation of the interactive programming session). For details, see *Interrogate the RNS Neurostimulator* on page *79* and *Data Retention* on page *107*.

PROGRAMMING

Select the light blue **PROGRAMMING** tile to access the **PROGRAMMING** screen. Programming sets, which can include changes to ECoG capture settings, changes to detection settings, and changes to stimulation settings, are selected, modified and programmed via the programmer **PROGRAMMING** screen. For details, see *Select Programming Set* on page *86*, *Test Stimulation Before Programming* on page *87* and *Program the RNS Neurostimulator* on page *89*.

ECOG LIBRARY

Select the orange **ECOG LIBRARY** tile to open the **ECOG LIBRARY**. The **ECOG LIBRARY** displays thumbnails of all ECoGs stored for the current patient. This functionality is not typically used on the programmer, and it requires Internet connectivity and being logged in to the PDMS. For details, see *Review ECoG Library* on page *20*.

> ***Note:*** *You must be logged in to the PDMS to access the ECoG Library screen. If you are connected to the Internet but not logged in, the* ***PDMS LOG IN*** *screen opens when you select* ***ECOG LIBRARY****, prompting you to log in. (See Log In to the PDMS on the RNS Programmer on page 75.)*
>
> ***Note: ECOG ASSISTANT*** *functionality is not available on the RNS Programmer; it is available only by accessing PDMS using a personal computer.*

LIVE ECOGS

Select the light green **LIVE ECOGS** tile to view and save a real-time ECoG. For details, see *View Live ECoGs* on page *85*.

TYPICAL RNS PROGRAMMER WORKFLOW

OVERVIEW

The following activities are recommended at a follow-up visit:

- Log in to the RNS Programmer. See *Power On the Programmer* on page *70*.
- Interrogate the RNS Neurostimulator. See *Interrogate the RNS Neurostimulator* on page *79*.
- Review measured battery voltage and electrode impedance. These are measured routinely during interrogation. See *Review Neurostim Info* on page *81*.
- View live ECoGs. See *View Live ECoGs* on page *85*.
- Select a shared programming set and carefully review pending programming changes. Make any additional changes to settings as needed. See *Select Programming Set* on page *86*.
- If stimulation settings are changed, be sure to test the patient's tolerance for the new settings before programming. See *Test Stimulation Before Programming* on page *87*.
- Program the new settings into the neurostimulator. See *Program the RNS Neurostimulator* on page *89*.

INTERROGATE THE RNS NEUROSTIMULATOR

Following successful log in to the RNS Programmer, from the Start Screen access is provided to interrogate the RNS Neurostimulator, which begins an interactive session.

To interrogate the RNS Neurostimulator means to identify it, perform routine tests and measurements, and retrieve currently programmed settings and stored data from it. Follow these steps to interrogate:

1. Connect the wand to the USB port on the programmer.

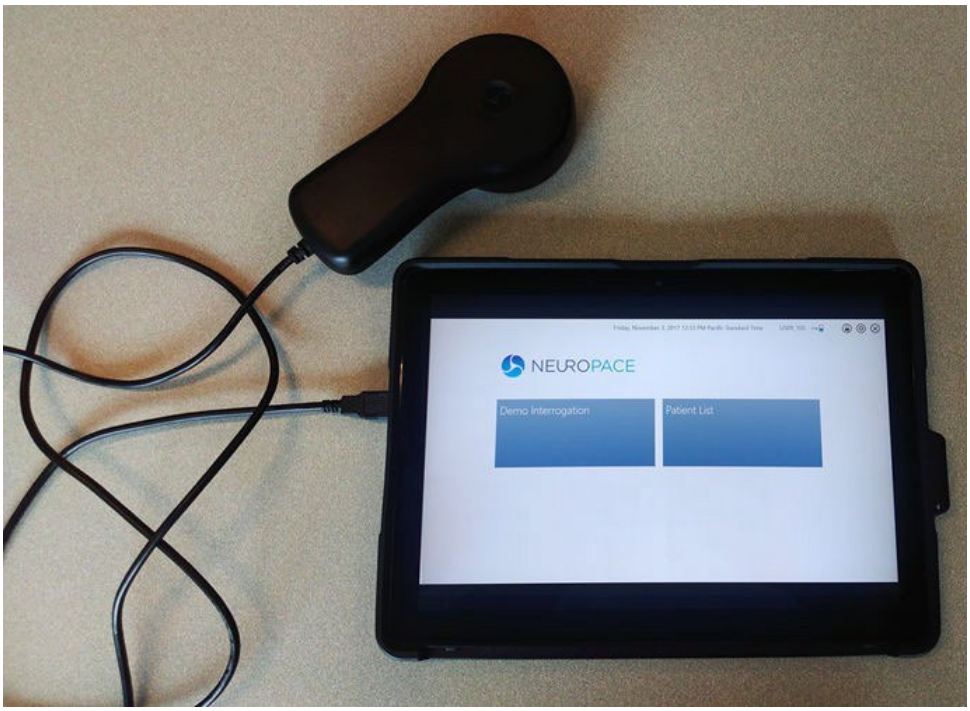


Figure 76 Programmer with connected wand

2. Place the wand within approximately 1 inch of the neurostimulator, concave side of wand facing the neurostimulator. Then select **INTERROGATE** from the Start screen, or from the **HOME** screen select the green **INTERROGATE** tile. The wand must be held in place over the neurostimulator for interrogation to succeed.

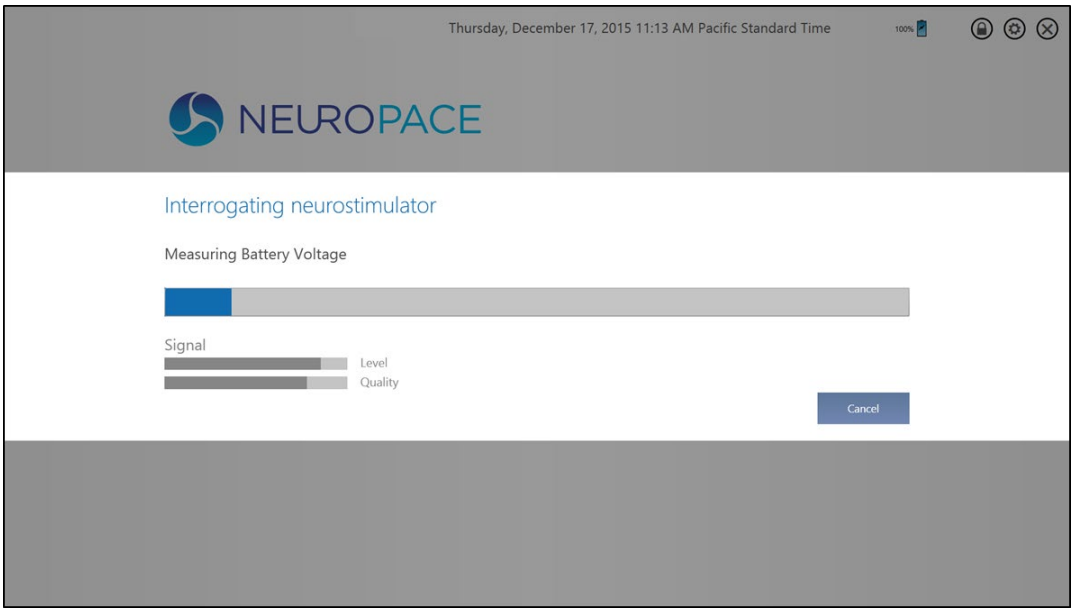


Figure 77 Interrogating neurostimulator dialog—interrogation in progress

The **INTERROGATING NEUROSTIMULATOR** dialog shows progress and the **HOME** screen appears when complete.

The dialog has bars that show the **LEVEL** and **QUALITY** of the **SIGNAL**. The **LEVEL** measures the strength of the communication between the RNS Neurostimulator and the RNS Programmer. The **QUALITY** measures the absence of electronic interference in the environment. For troubleshooting information regarding poor signal level or quality, see *Poor or No Communication Between the RNS Neurostimulator and the Programmer* on page *112*.

It may take from 10 seconds up to 5 minutes, depending on the amount of data to be retrieved. Interrogation does not significantly drain the neurostimulator battery.

When interrogation completes, the **HOME** screen appears, which is the launch point for all programming activities.

REVIEW NEUROSTIM INFO

Select **NEUROSTIM INFO** from the **HOME** screen to open the **NEUROSTIM INFO** screen. The **NEUROSTIM INFO** screen provides information about the neurostimulator, including status of detection, stimulation, alerts, battery voltage, and electrode impedance.

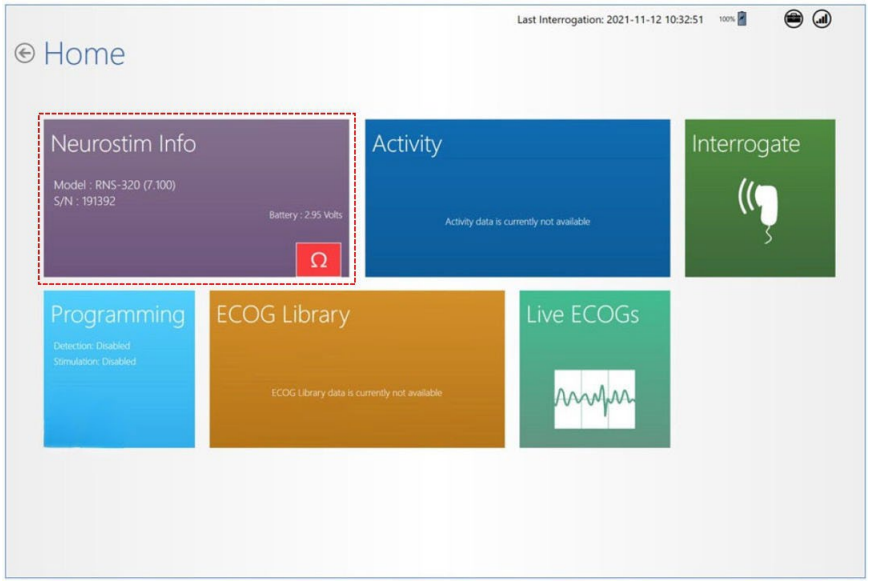


Figure 78 Select Neurostim Info tile on Home screen

Figure 79 Neurostim Info Screen

The **NEUROSTIM INFO** screen provides information about the neurostimulator, including:

- At upper left, whether **DETECTION** and **STIMULATION** are **ENABLED** or **DISABLED** and Alerts, if any. For a list of alerts and their meaning, see *Alerts* on page *104*.

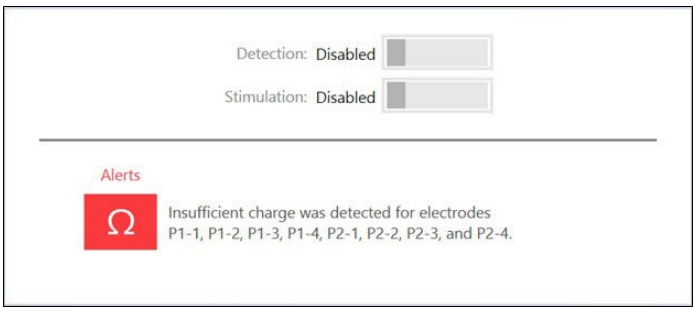


Figure 80 Neurostimulator information

Note: *The alert for insufficient charge on all electrodes is characteristic of new implants until you create the recording montage and measure impedance, as is normally done in the operating room.*

- At upper right, **MODEL**, serial number (**S/N**) and **LAST PROGRAMMED** date and time (24-hour time).

Figure 81 Model, serial number and last programmed date and time

- At middle right, **MEASURED BATTERY VOLTAGE** with **MEASURE** button. The early, mid and late life voltage ranges are displayed to give context to the measured voltage. See *Significance of Battery Voltage* on page *84*.

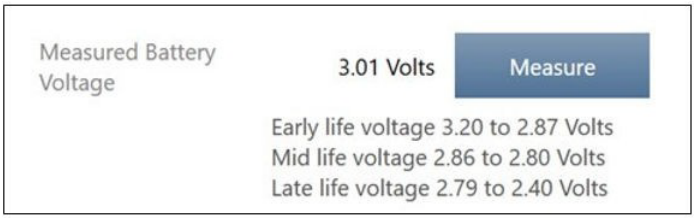


Figure 82 Measured Battery Voltage

- At lower right, measured impedance for electrodes on the **PORT #1** and **PORT #2** leads.

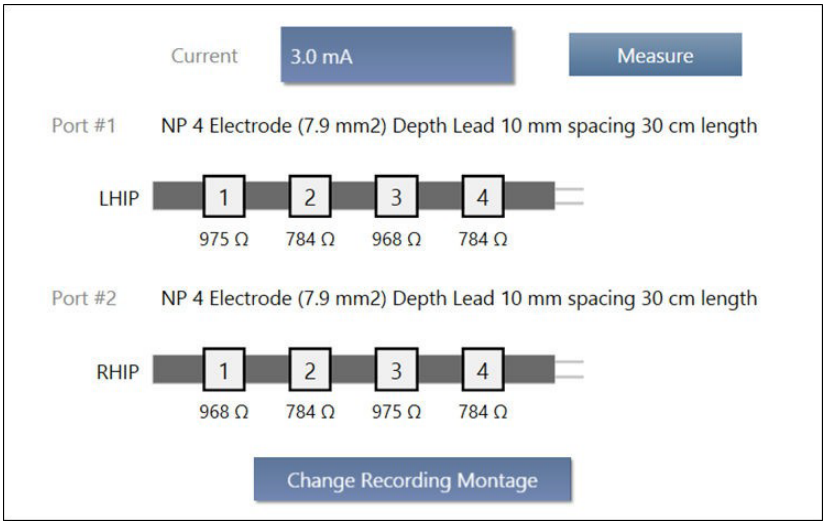


Figure 83 Measured impedance on leads

- Buttons to **MEASURE** impedance manually using the amount of **CURRENT** selected. (It is measured routinely during interrogation.)
- A button to **CHANGE RECORDING MONTAGE** as explained under *Create the Recording Montage* on page *93*.

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 84 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 below.

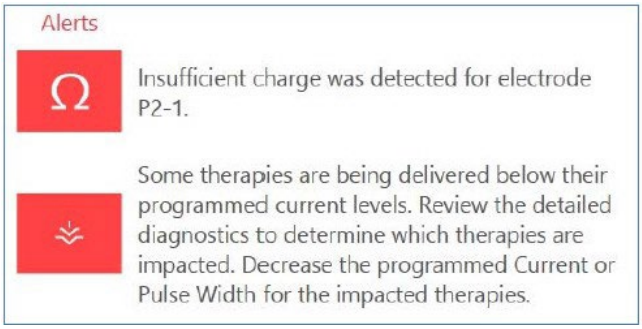


Figure 85 Alerts when there is insufficient charge to deliver therapies

For troubleshooting information, refer to *Abnormal Lead Impedance (>3500 Ohms or <250 Ohms)* on page *108*; and *Insufficient Charge* on page *111*.

SIGNIFICANCE OF BATTERY VOLTAGE

The programmer displays current battery voltage and the early, middle, and late life battery voltage ranges to provide an understanding of remaining neurostimulator battery life. The elective replacement indicator (ERI) appears approximately three months before the neurostimulator reaches end of service (EOS). For example, for the RNS Neurostimulator model RNS-320, normal 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 programmer notifies you on screen by showing the elective replacement indicator (ERI).

VIEW LIVE ECOGS

Note: *The wand must be held within approximately 1 inch of the neurostimulator to acquire live ECoGs.*

With the wand in place over the RNS Neurostimulator, 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 86 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 (see *Configure Detection: Define and Modify Detection Settings* on page 52).

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 programmer, not in the neurostimulator memory, and are uploaded to the PDMS when the programmer is connected to the Internet.*

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 clinician should be aware of possible sensing artifacts when assessing the ECoG recordings.

SELECT PROGRAMMING SET

Sharing a programming set makes it available to the targeted user or programmer when connected to the Internet. Shared programming sets are automatically downloaded and saved locally to the programmer when connected to the Internet.

When connected to the Internet on the RNS Programmer, an envelope icon will appear on the **PROGRAMMING** tile of the RNS Programmer **HOME** screen, as shown.

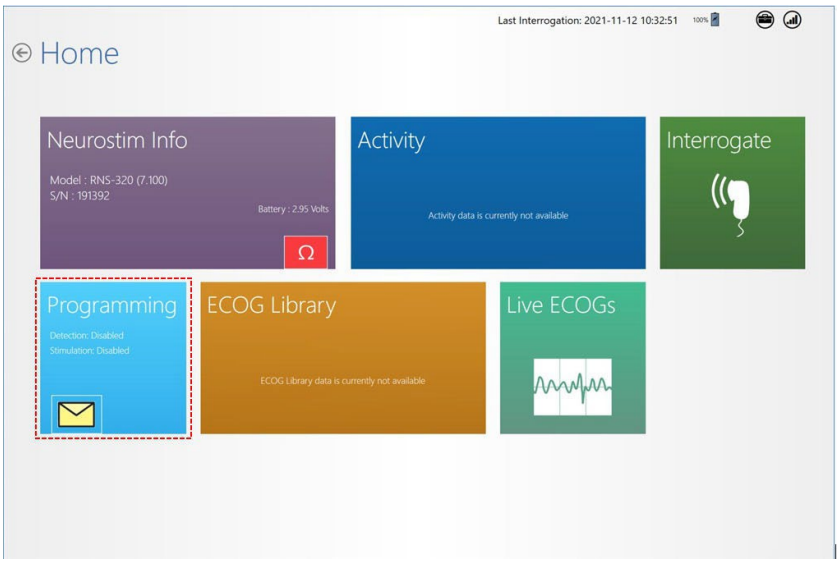


Figure 87 Envelope on Programming Tile indicates a new programming set

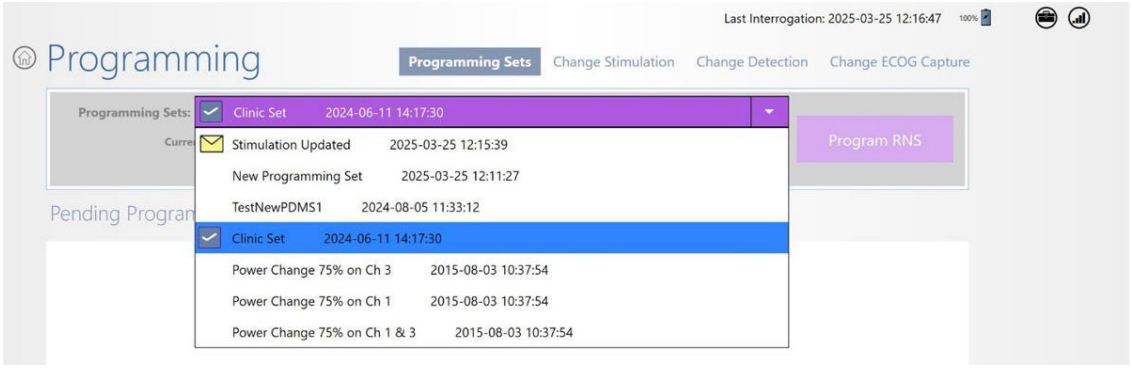


Figure 88 Envelope next to the new programming set in Programming Sets field

1. Select the **PROGRAMMING** tile to open the **PROGRAMMING SETS** screen, and touch in the **PROGRAMMING SETS** field to see the list of available program sets.
   - Programming sets are listed by date created, most recent first. (If someone else shared the programming set with you, the name of the programming set includes the username of the person who shared it or created it, in parentheses.) **At the top of the list of programming sets, the name of the new programming set should be visible, with the envelope icon next to it.** Select that new programming set.

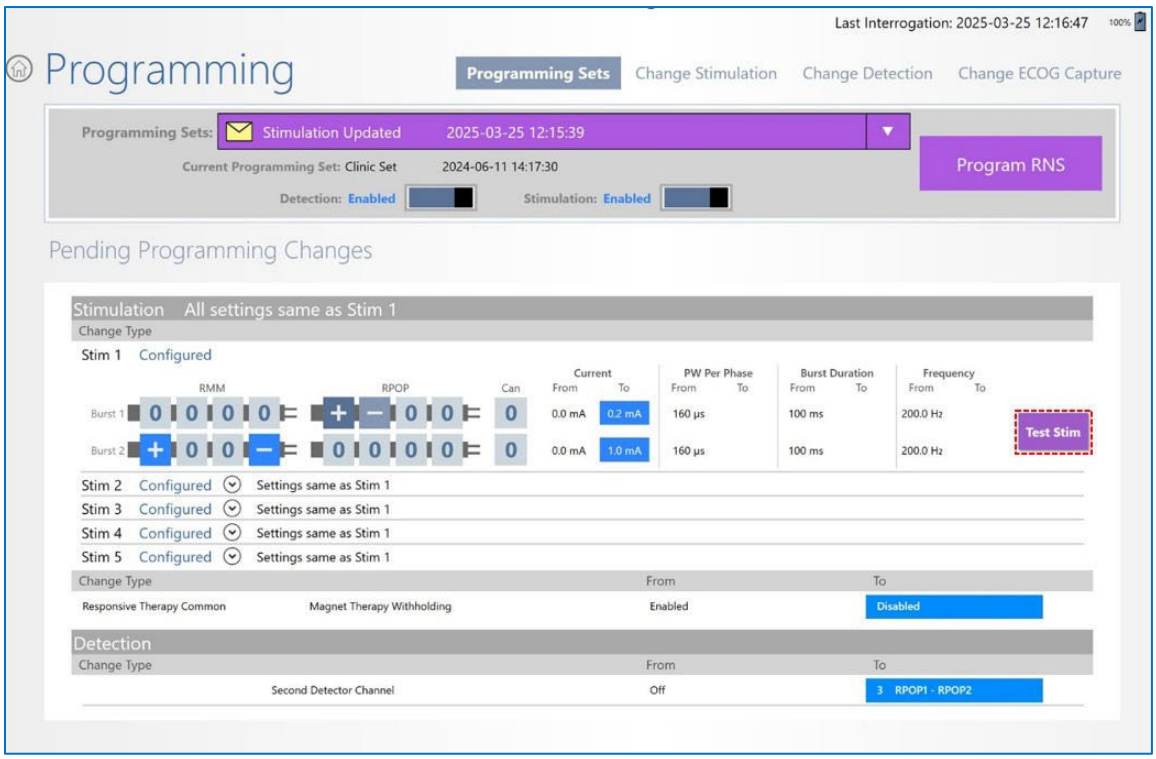


Figure 89 New programming set with envelope selected

2. When you select the new programming set, it automatically shows what is changed on the **PROGRAMMING SETS** screen. Blue items have changed. It is available for immediate programming to the target patient's neurostimulator.
3. If you are not satisfied with the pending changes, select the desired button to **CHANGE DETECTION**, **CHANGE STIMULATION** or **CHANGE ECOG CAPTURE**, and after making changes, select **REVIEW ALL CHANGES** and then **PROGRAM RNS**.

TEST STIMULATION BEFORE PROGRAMMING

Before enabling responsive therapy, it is important to test stimulation to make sure it is well tolerated by the patient and there are no undesired changes in the ECoG, such as afterdischarges. You must test stimulation in an interactive programming session, using the RNS Programmer and Wand with the patient present.

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

1. On the Programmer Home Screen, select **PROGRAMMING**.
2. On the **PROGRAMMING** screen, select the new programming set with changed stimulation settings.

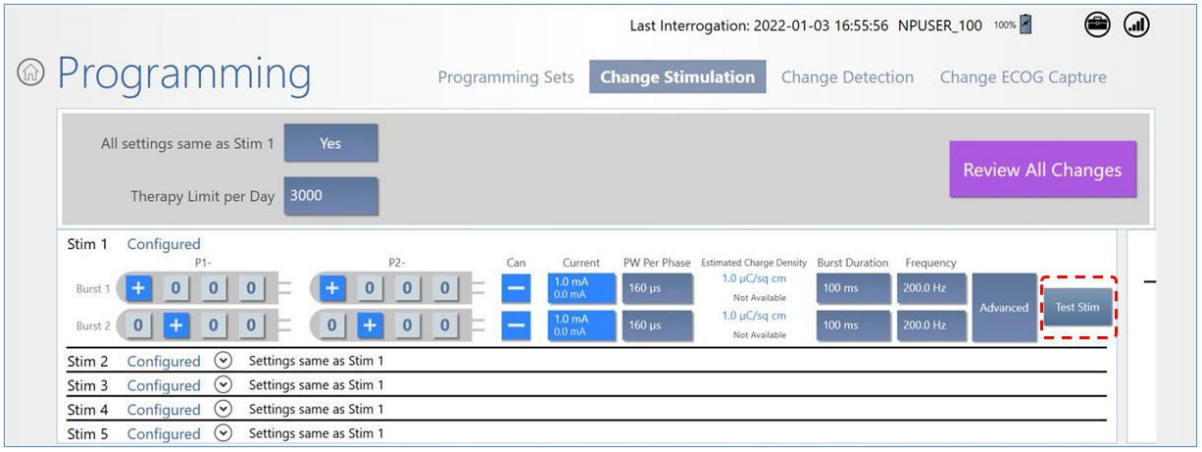


Figure 90 Select Test Stim button on the Programmer

3. While holding the wand over the neurostimulator, select **TEST STIM** on the far right of the row to open the **TEST STIMULATION** screen and test the new stimulation settings. Note that the **TEST** button is not available if adaptive therapy is on (see *Optional Advanced Settings* on page *65*).
4. An ECoG is running when the screen opens. Select **DELIVER** to deliver the test burst. Select **STOP/ STORE** when desired to stop recording.

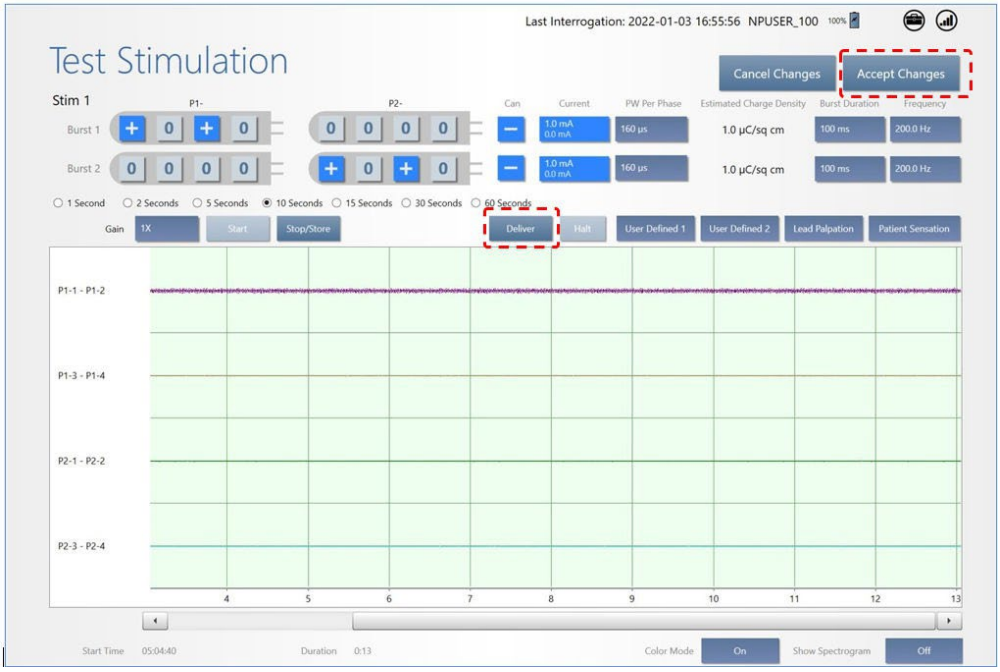


Figure 91 Test Stimulation screen

5. You can adjust settings and retest while this screen is open. To exit test stimulation, select **ACCEPT CHANGES** or **CANCEL CHANGES** at upper right.
   - Stimulation may evoke visual, olfactory, auditory, taste, sensory or motor responses.

- Test stimulations should be delivered to each electrode individually (electrode to neurostimulator) to determine whether there are acute side effects from stimulation.
- Habituation to side effects resulting from stimulation has been observed; however, it is not advised to program settings that cause patient discomfort.
- Avoid stimulation settings that cause an electrographic afterdischarge.

Caution: After Discharge Activity
If evidence of after discharge activity resulting from stimulation is seen either on stored ECoGs or during test stimulation delivery, stimulation parameters should be adjusted to prevent such occurrence.

PROGRAM THE RNS NEUROSTIMULATOR

1. To activate the configured detection and therapy, make sure **STIMULATION** and **DETECTION** are set to **ENABLED** at upper center.
2. When 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 until complete.

Figure 92 New programming set now programmed shows checkmark

OTHER RNS PROGRAMMER USE SCENARIOS

RNS PROGRAMMER USE IN THE CLINICAL ENVIRONMENT WITHOUT INTERNET ACCESS

Download a Programming Set

Downloading a programming set to the programmer requires an Internet connection and logging in to the PDMS. See *Power On the Programmer* on page *70* and *Log In to the PDMS on the RNS Programmer* on page *75*. A downloaded programming set is available for programming when the RNS Programmer is not connected to the Internet.

STEPS TO DOWNLOAD A PROGRAMMING SET TO THE PROGRAMMER FOR OFFLINE USE

To download a programming set and save it locally to the programmer for offline use, follow these steps:

1. Using the programmer, navigate to the Start screen. (If you did not just log in to the programmer, use the Home button at upper left or Back button at upper right, if necessary, to reach the Start screen.) Reaching the Start screen ends any prior interactive programming session.

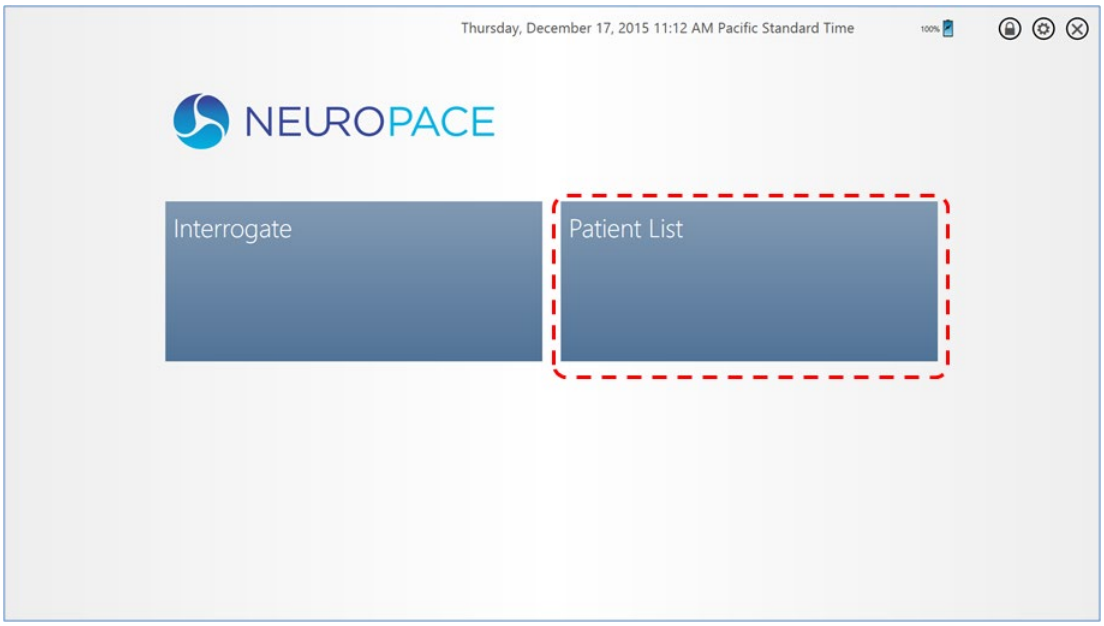


Figure 93 Select Patient List on the Start screen

2. Select the **PATIENT LIST** tile on the programmer Start screen. This opens the **PATIENT LIST** on the PDMS.
3. Select the desired patient from the patient list. The **PDMS HOME** screen opens. Note this is different than the programmer **HOME** screen.

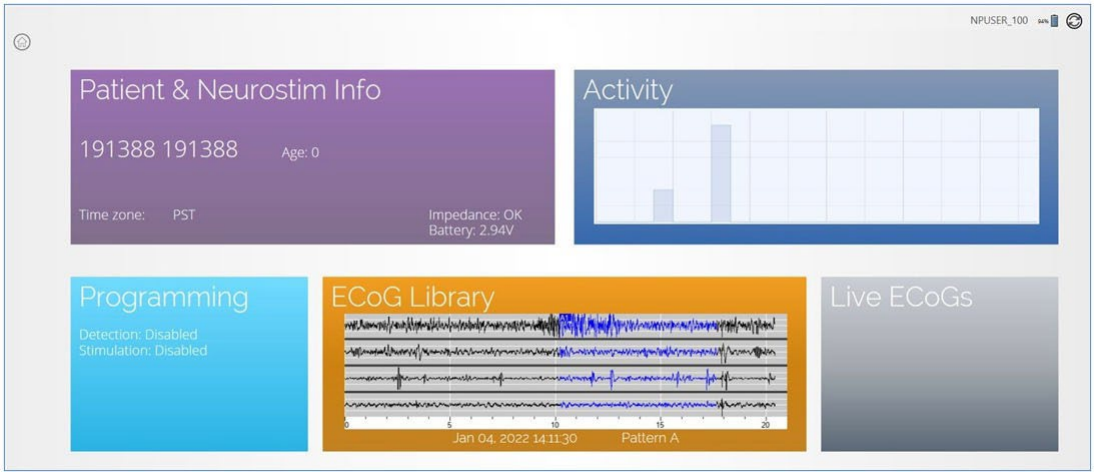


Figure 94 PDMS Home screen

4. Select the **PROGRAMMING** tile. The **PROGRAMMING SETS** screen opens.
5. Touch in the **PROGRAMMING SETS** field to find and select the name of the programming set you want to download to the programmer. They are listed by date, most recent first. (If someone else created or shared the programming set with you, the name of the programming set includes the username of the person who created or shared it, in parentheses.) The **SHARE** button becomes active.

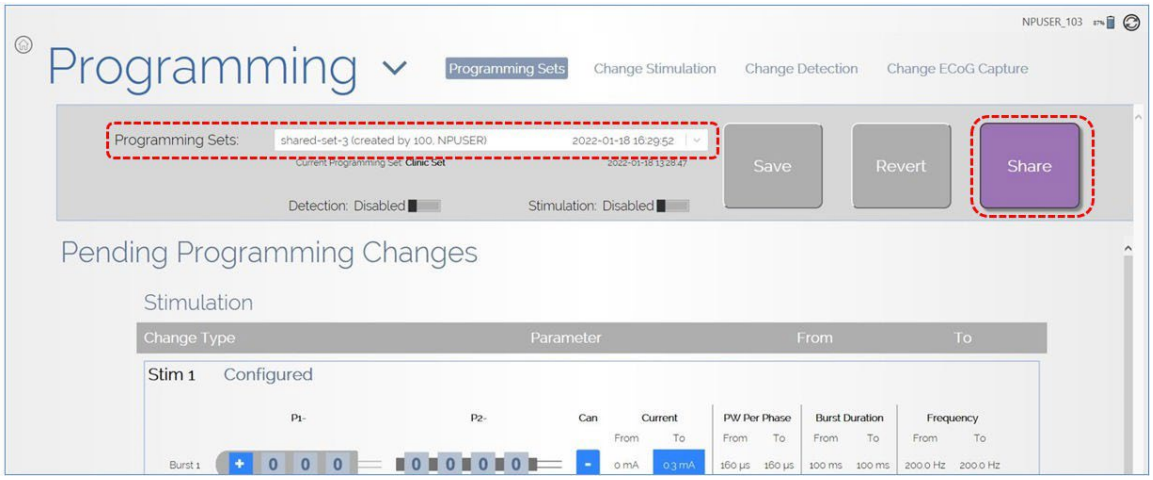


Figure 95 Programming Sets screen

6. Select the **SHARE** button. The **SHARE PROGRAMMING SET** dialog opens. On the programmer, it includes a checkbox named **DOWNLOAD TO THIS PROGRAMMER NOW** along with the other sharing options.

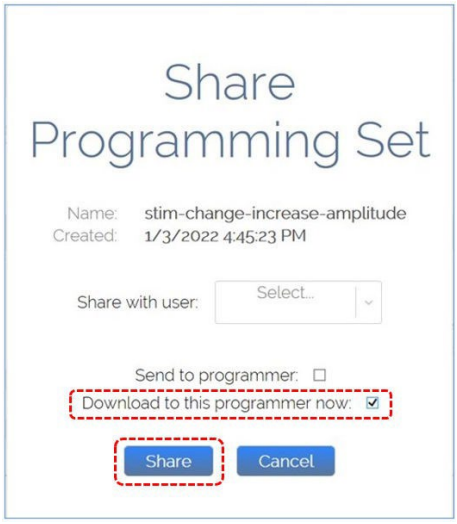


Figure 96 The SHARE PROGRAMMING SET dialog on the PDMS using the programmer

7. Select the **DOWNLOAD TO THIS PROGRAMMER NOW** checkbox and then select the **SHARE** button.

A **PDMS TRANSFER** dialog appears briefly and closes when download is complete. The downloaded programming set has been saved locally to the programmer. It will be available on the programmer when there is no Internet connection. Using the programmer offline, you can select the downloaded programming set for programming after you interrogate the target patient's neurostimulator.

Note: *The downloaded programming set is not available if the programmer has Internet connection.*

RNS Programmer Use in the Surgical Environment

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 programmer. Upon initial implant, you must configure and program a recording montage to enable all other programming functions. Programming sets are associated with a particular montage. When the montage is modified, the programming sets associated with that montage become unavailable, requiring the creation of new programming sets. 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

The figure below identifies neurostimulator **Port #1** and **Port #2** with their leads extending out of the ports.

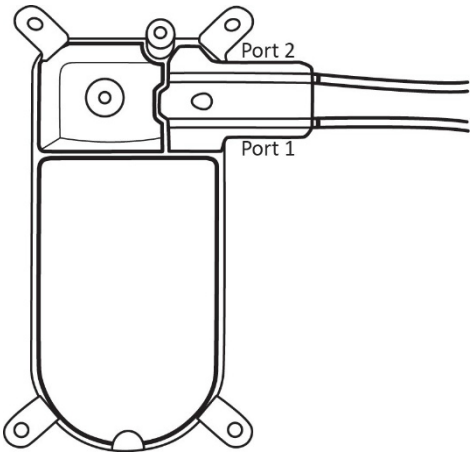


Figure 97 RNS Neurostimulator port #1 and #2 locations. Port #1 is closer to the center of the neurostimulator and port #2 is closer to the edge.

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

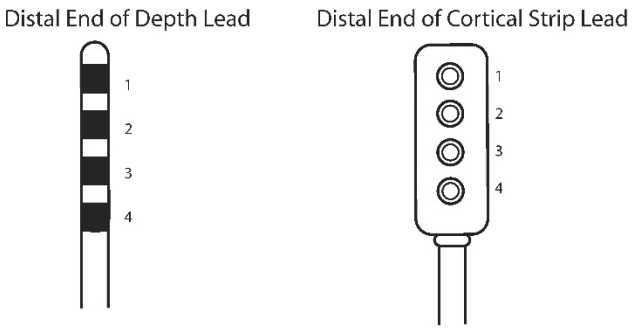


Figure 98 For both lead types, electrodes are numbered 1 through 4. Electrode 1 is most distal.

CREATING THE MONTAGE

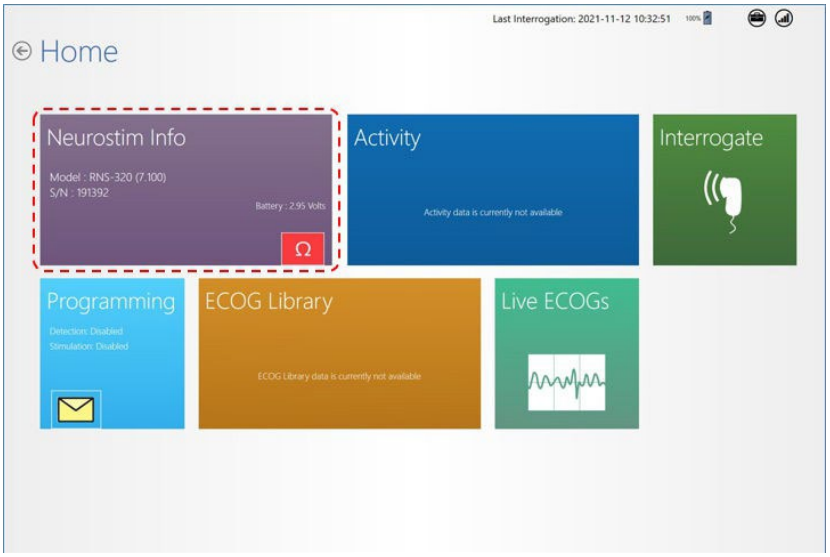


Figure 99 Select NEUROSTIM INFO on HOME screen

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

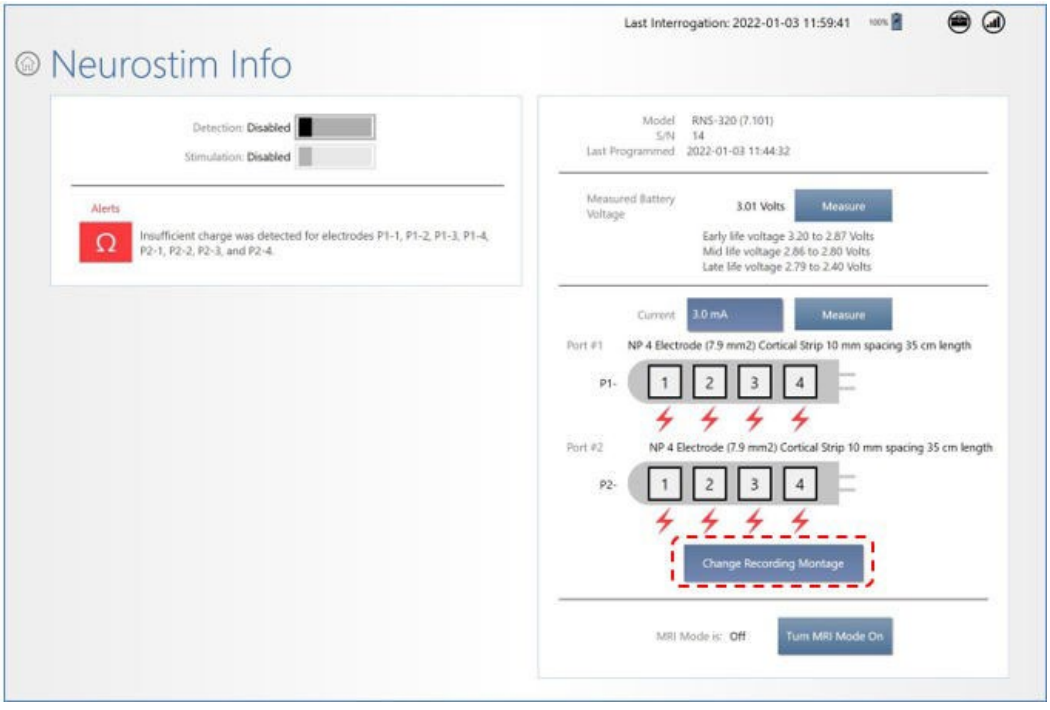


Figure 100 NEUROSTIM INFO Screen

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

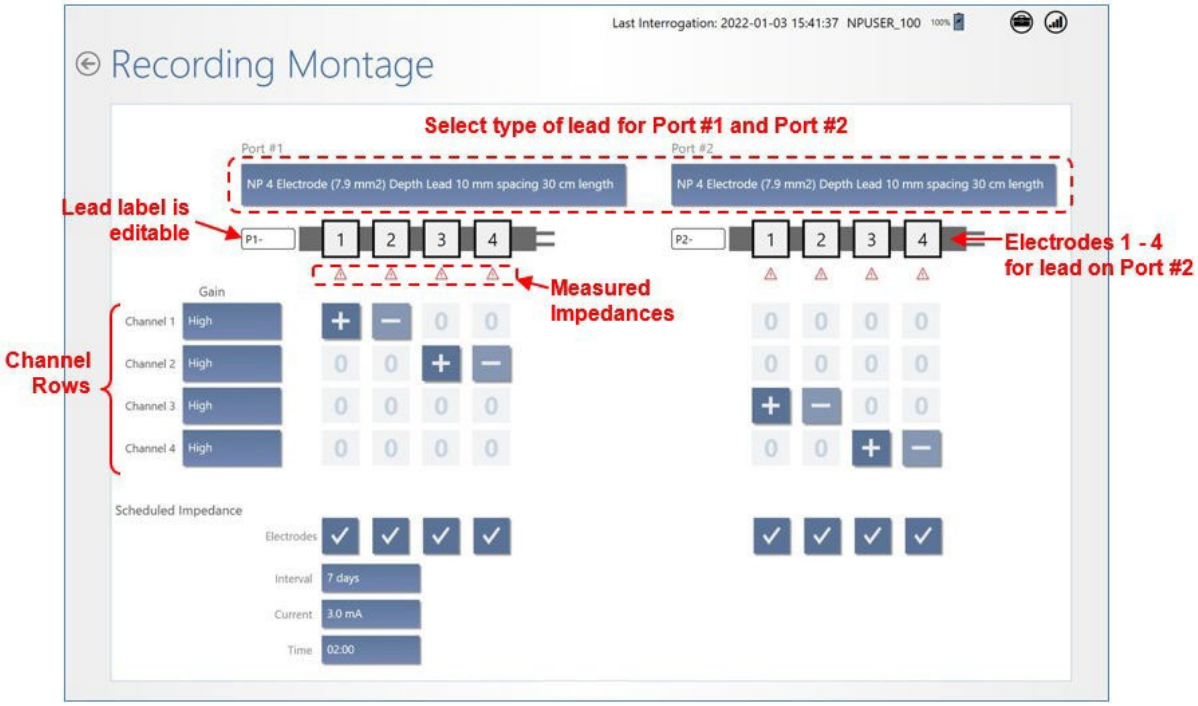


Figure 101 RECORDING MONTAGE screen

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.*

3. **At Neurostimulator Implant and When Changing Leads:** Navigate to **PORT #1** and/or **PORT #2**. Just below the port label select the field that says **NONE** and from the dropdown list select the type of lead installed in that port.

4. **Assign Electrodes to Channels:**

   Default Configuration:

   CHANNEL 1 through 4 are shown as preset electrode assignments.

   Assignment Modification:

   Deselect the current assignments by selecting the small square fields.

   Select the desired electrode configuration:

   - Positive input [+]
   - Negative input [–]
   - Zero input [0]

   Sensing Operation:

   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 programmer 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.

1. Select **REVIEW ALL CHANGES** at upper right.

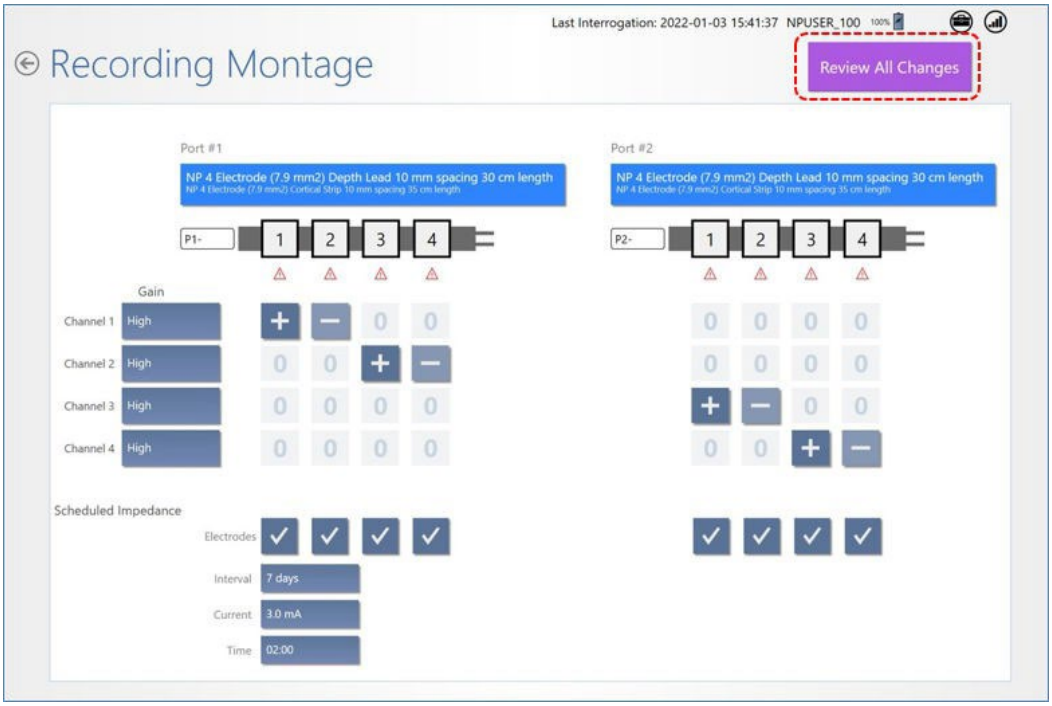


Figure 102 Recommended initial montage settings

All **PENDING PROGRAMMING CHANGES** appear on the **PROGRAMMING SETS** screen for your review before programming. Scroll down if necessary to see all the changes.

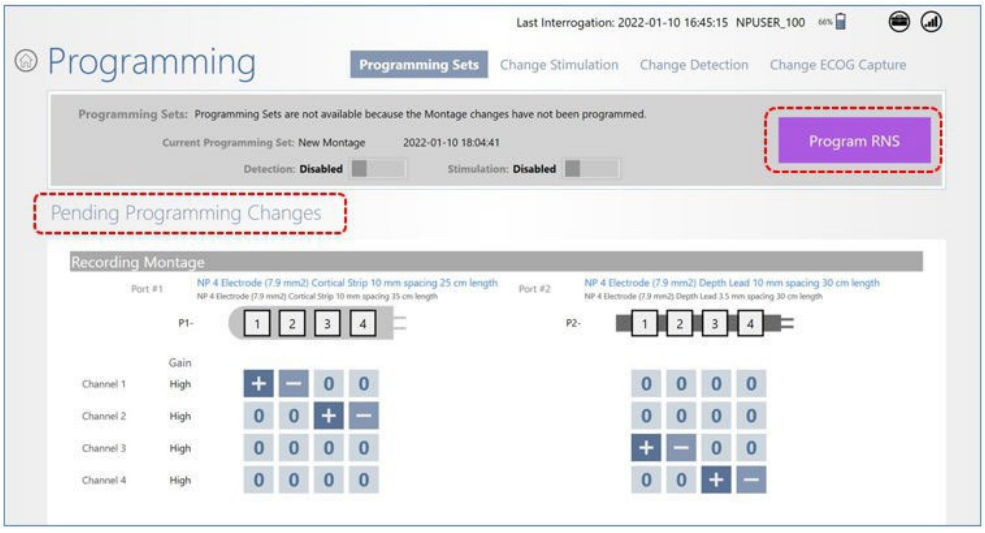


Figure 103 Pending Programming Changes for montage

2. 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.

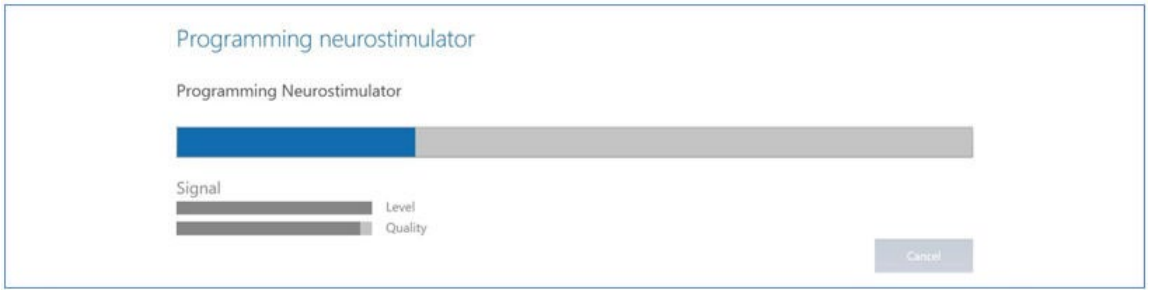


Figure 104 Programming neurostimulator dialog shows progress of programming

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.

PROGRAM DEFAULT DETECTION SETTINGS

Upon first use with a new patient, you must select one of three default programming sets. This is usually configured in the operating room immediately after implantation. The default sets are used to quickly gather ECoGs for a patient, which you can then use to define detection settings specific to the patient. Creating settings specific to a patient is covered in *Phase 2: Define Detection Settings* on page *54*.

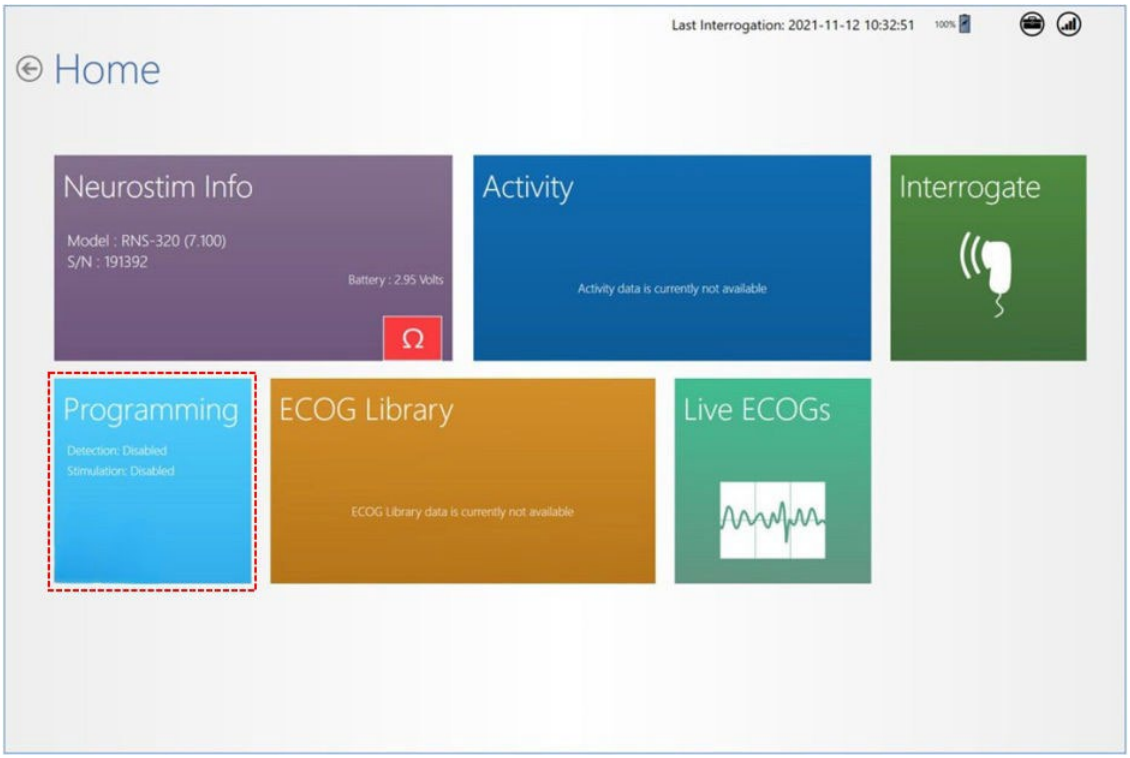


Figure 105 Select Programming tile on Home screen

1. Select **PROGRAMMING** from the **HOME** screen.
2. On the **PROGRAMMING SETS** screen, select the down-arrow at the right end of the **PROGRAMMING SETS** field to view the available programming sets. The three default programming sets are named beginning with *** DEFAULT * POWER CHANGE 75% ON CH 3**. (If the programmer is connected to the Internet, *** DEFAULT *** does not appear before the name.)

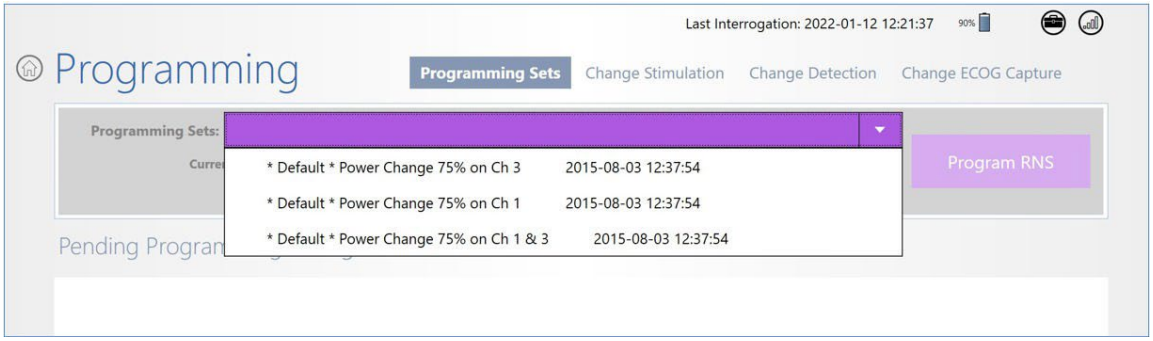


Figure 106 View available programming sets

3. Select one of the three default programming sets, each of which includes default detection settings. In the usual case, a patient has two active leads and therefore the recommended default programming set is **Power Change 75% on CH 1 & 3 (Default)**. If only one lead is implanted, the two- channel option will not appear in the list. The two other default programming sets are designed to detect on only one lead.

   Power change 75% is a detection setting that captures any large changes in the signal.

4. Make sure **Detection** is **Enabled**. Select the button next to the label **Detection:** Toggle the button from **Disabled** to **Enabled**.

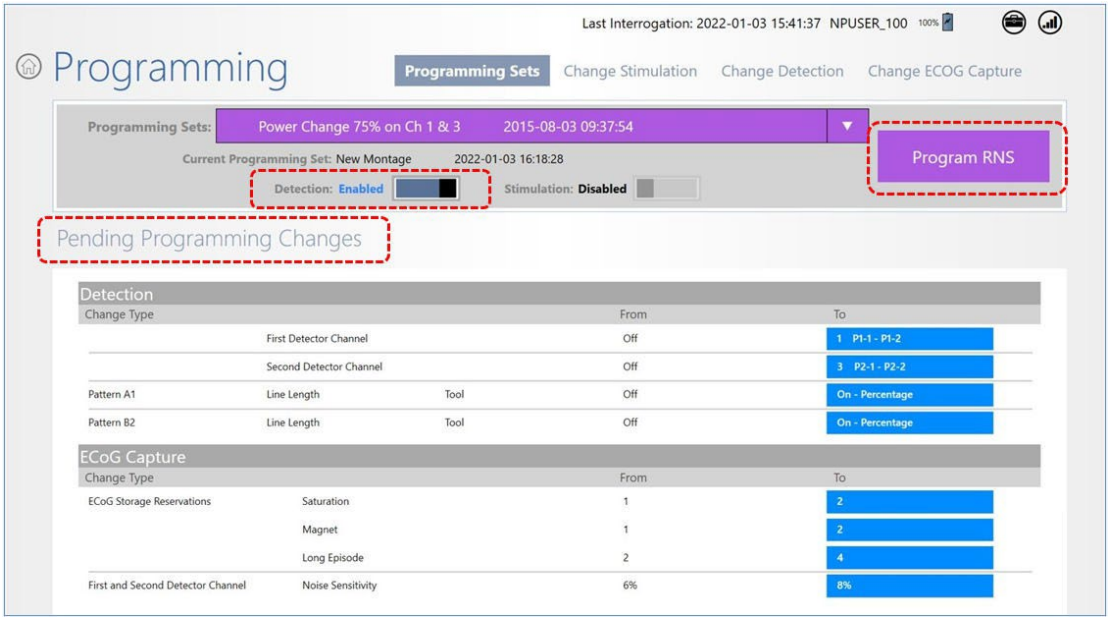


Figure 107 Make sure Detection is enabled

5. Once you are satisfied with the new settings, place the wand within approximately 1 inch of the neurostimulator and select **PROGRAM RNS**. A **TELEMETRY INFORMATION** dialog reports that "Detection is Enabled and Responsive Therapy is Disabled," and prompts you to select **CONTINUE** or **CANCEL**.

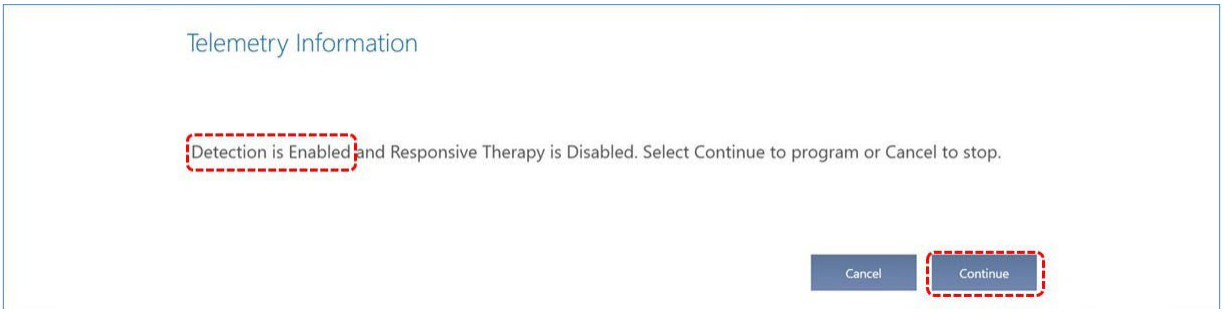


Figure 108 Telemetry Information dialog to confirm programming

6. Make sure the message reports that **DETECTION** is **ENABLED**, keep the wand in place and select **CONTINUE** to proceed with programming, or **CANCEL** to cancel programming and return to the previous screen. When you select **CONTINUE**, the **PROGRAMMING NEUROSTIMULATOR** dialog shows programming progress until complete.

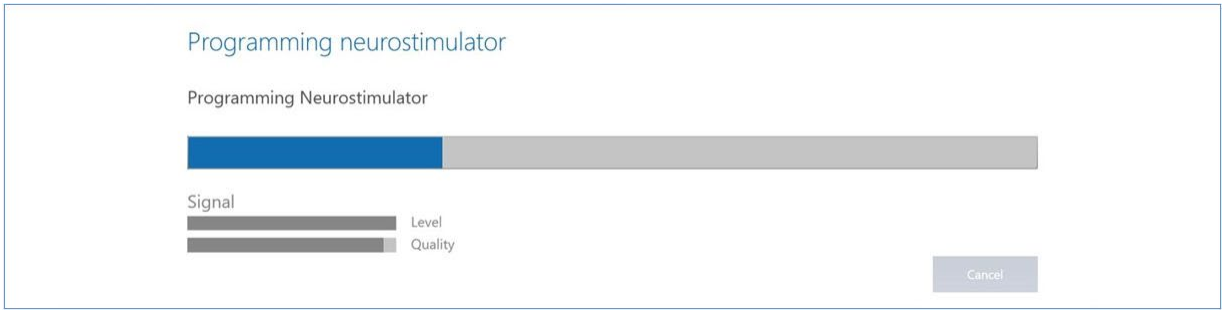


Figure 109 Programming neurostimulator dialog shows progress of programming

The **PROGRAMMING SETS** field displays the default detection set name with a checkmark when programming is complete. The **PROGRAM RNS** button becomes inactive, and no pending changes are indicated.

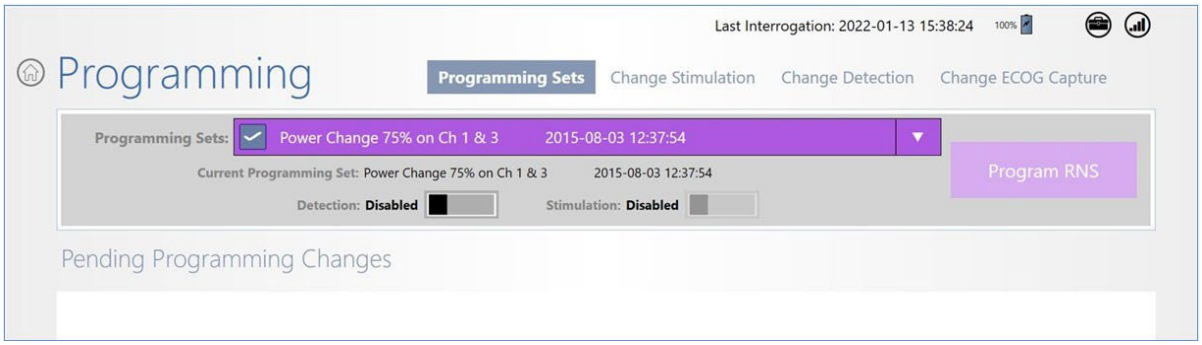


Figure 110 PROGRAMMING SETS screen after programming a default programming set

EXPORT AND IMPORT DEVICE SETTINGS FOR NEUROSTIMULATOR REPLACEMENT

The programmer 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 programmer without using the PDMS—exported settings are kept locally on the programmer—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.

EXPORT NEUROSTIMULATOR SETTINGS

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

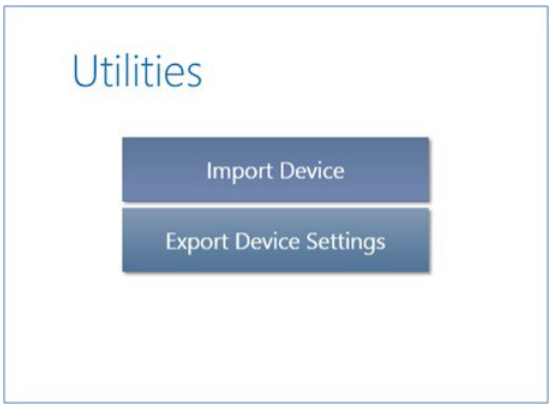


Figure 111 Utilities dialog

3. Select **EXPORT DEVICE SETTINGS** to complete the export procedure. All current neurostimulator settings are stored on the programmer ready for import.

Note: *The programmer maintains a single set of device settings, retaining only the most recent export from any neurostimulator. Each new export operation from any neurostimulator completely overwrites the existing settings. When settings are successfully imported and programmed to a new neurostimulator, they are automatically cleared from the programmer's storage.*

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. The **UTILITIES** dialog opens (see 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 programmer. It also notifies you if the programmer has no settings that came from a compatible neurostimulator.

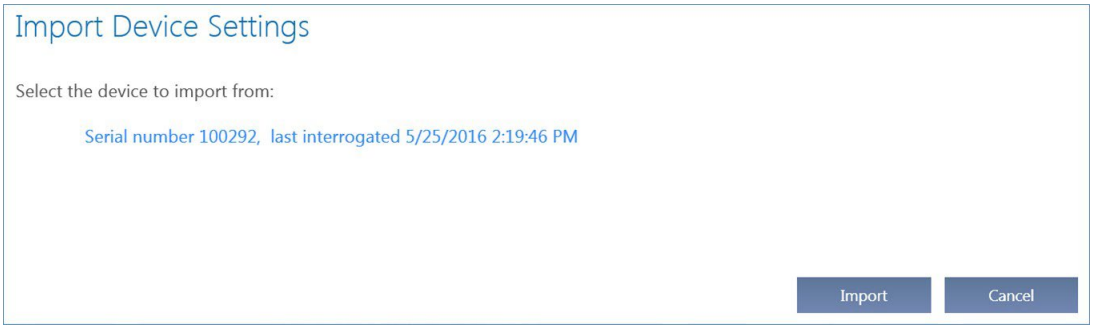


Figure 112 Import Device Settings dialog

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 programmer **PROGRAMMING** screen opens. The active (purple) **PROGRAM RNS** button indicates pending settings are ready to be programmed.

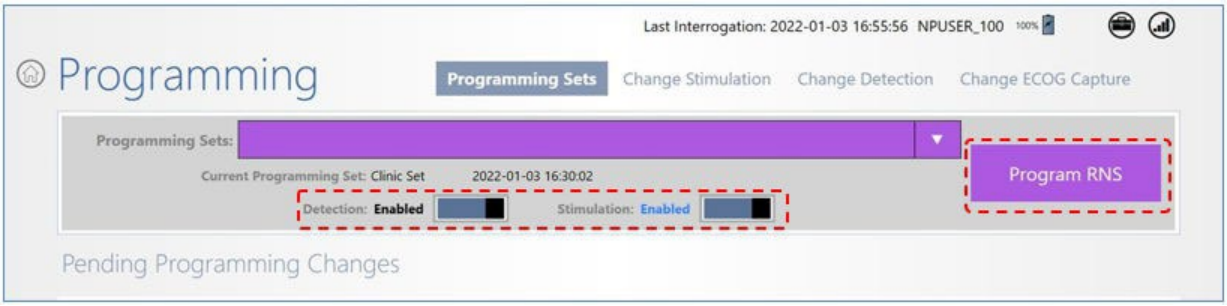


Figure 113 Program RNS button active — pending settings ready to be programmed

   - 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 programmer when programming is complete. If you do not complete this step, the settings will remain available on the programmer.

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* *Recommended Therapy Modifications After Observing Clinical Response on page 68.*

ALERTS

Alerts within the PDMS appear on PDMS in PC viewing screens and programmer viewing screens. The alerts are identical.

On the **HOME SCREEN**, four alert symbols may appear on the **PATIENT & NEUROSTIM INFO** tile, as illustrated below. Alerts also can appear on the **PATIENT LIST** screen. See the following table for explanations of specific alert symbols that may be displayed on screen, and what to do about them.

Figure 114 Alert symbols on Patient & Neurostim Info tile

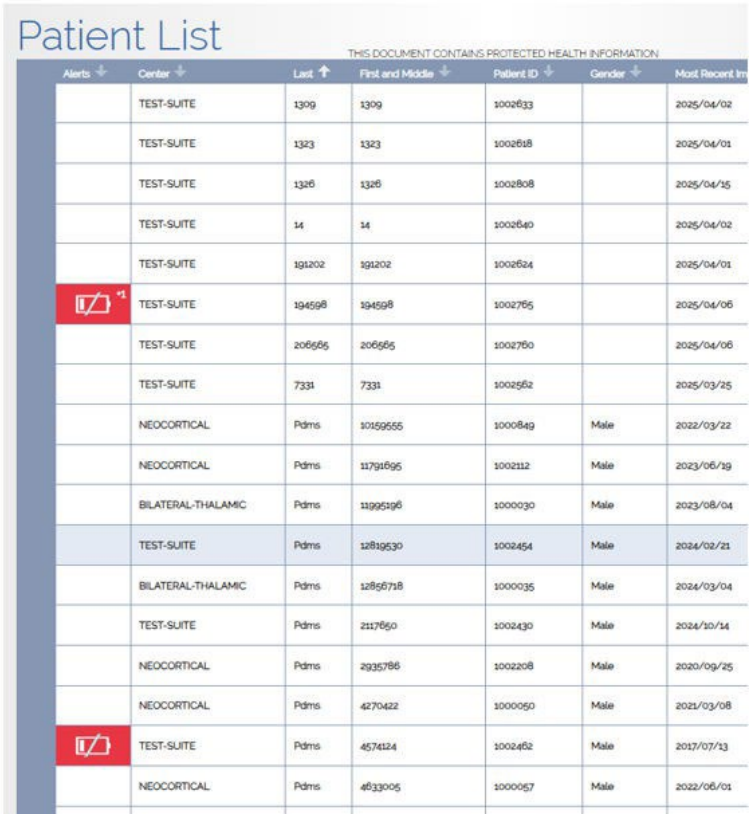


Figure 115 Patient List with alert symbols

Regarding Resets: Some alerts regard resets. 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 Customer Support (see *Contact NeuroPace* on back page).

Table 5 Alerts

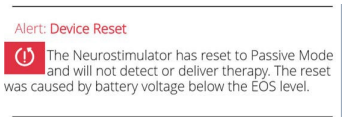
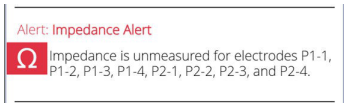
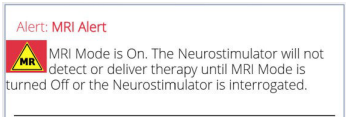
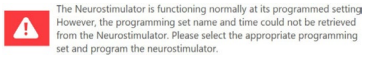
PDMS Screen Alert Symbol	Description	Action to Consider
	Alert: Low Battery Reset A battery voltage will be displayed.	This alert appears when the neurostimulator reaches End of Service (EOS). Neurostimulator replacement is recommended.
	Alert: Device Reset The Neurostimulator has reset to 'Passive Mode' and will not detect or deliver therapy.	There are several kinds of device resets. Some are recoverable and others are not. See additional information, 'Reset' in the glossary. If the reset is not recoverable, neurostimulator replacement is recommended.
	Alert: Battery voltage is at Elective Replacement Indicator (ERI) level. A battery voltage will be displayed.	Elective Replacement Indicator (ERI) appears at approximately three months prior to End of Service. Neurostimulator replacement is recommended.
	Impedance Alert Impedance is unmeasured/ insufficient charge was detected ... for electrodes P1-1, P1-2, P1-3, P1-4, P2-1, P2-2, P2-3, and P2-4.	When all electrodes are unmeasured, it is characteristic of a newly implanted device until a recording montage has been created. Create a montage and measure impedance again. If less than all electrodes have unmeasured impedance, first try to measure impedance again. See instructions under *Electrode Impedance and Battery Voltage* on page *83*. Also refer to Troubleshooting for *Impedance Measurement Was Rejected / Test Request Was Rejected* on page *113* and *Insufficient Charge* on page *111*.

Table 5 Alerts

PDMS Screen Alert Symbol	Description	Action to Consider
	MRI Alert MRI Mode is On. The Neurostimulator will not detect or deliver therapy until MRI Mode is turned off or the Neurostimulator is interrogated.	For complete instructions, refer to the MRI Guidelines at this link: *https://www.neuropace.com/providers/physician-resources/?tab=mri-guidelines*.
	Tilt Alert Some therapies are being delivered below their programmed current levels. Review the detailed diagnostics to determine which therapies are impacted. Decrease the programmed Current or Pulse Width for the impacted therapies.	See *Configure Responsive Therapy* on page *62*.
	Insufficient charge was detected for electrodes P1-1, P1-2, P1-3, P1-4, P2-1, P2-2, P2-3, and P2-4.	See troubleshooting steps for *Insufficient Charge* on page *111*.
	Alert: The Neurostimulator is functioning normally at its programmed setting. However, the programming set name and time could not be retrieved from the Neurostimulator.	Please select the appropriate programming set and program the neurostimulator.

DATA RETENTION IN THE RNS SYSTEM

NEUROSTIMULATOR PROGRAMMED SETTINGS

The neurostimulator retains its programmed settings until it is programmed again. These include the recording montage, ECoG capture triggers and reservations, and the detection and stimulation settings.

STORAGE OF ECOGS AND NEUROSTIMULATOR ACTIVITY (DIAGNOSTICS)

Between interrogations by the patient or a clinician, the neurostimulator stores ECoGs and neurostimulator activity events up to its storage limit. (Neurostimulator activity events are also known as diagnostics, which include, for example, detection and stimulation events and magnet swipes.) Once the memory for ECoGs or diagnostics is full, the neurostimulator will store new data by overwriting the oldest ECoG or diagnostics. Reserved ECoGs are overwritten only by newer ECoGs of the same ECoG capture trigger type.

- The maximum number of ECoGs stored on the neurostimulator depends on the capture duration you select in the ECoG capture settings (see *Configure ECoG Capture* on page *48* for details).
- The number of neurostimulator activity events that can be stored is not adjustable. However, the number of events that can be stored is large compared to the number of ECoGs, because the data size of each event is relatively small.

At each interrogation with the remote monitor or programmer, the neurostimulator transfers all stored ECoGs and diagnostics to the programmer or remote monitor, at which point the successfully transferred data is cleared from the neurostimulator.

- If the programmer or remote monitor is not connected to the Internet, the transferred data remains on the programmer or remote monitor hard drive. You cannot view ECoGs or diagnostics while stored on the programmer or remote monitor; it must be transferred to the PDMS before you can view it.
- When the programmer or remote monitor is connected to the Internet, the transferred data is automatically uploaded to the PDMS and cleared from the programmer or remote monitor memory. If automatic upload to the PDMS does not complete successfully, data is not lost. Data is cleared from the programmer or remote monitor only after a successful upload.
- Data is retained on the PDMS.

Note: Programming clears activity information (diagnostics) and ECoGs stored in the neurostimulator. *In case ECoGs or diagnostics have been stored after initiating an interactive session, be sure to interrogate the neurostimulator immediately prior to programming.*

Note: *ECoG capture triggers are inactive during programming.*

TROUBLESHOOTING THE PROGRAMMER

OVERVIEW

Note: *This section addresses only problems specific to the RNS Programmer. For troubleshooting information regarding other components of the RNS System, see the RNS System manual. For troubleshooting information regarding the NeuroPace Remote Monitor, see the NeuroPace Remote Monitor Manual.*

If the information in this section does not resolve the problem, contact NeuroPace Customer Support for further assistance (see *Contact NeuroPace* on back page).

For a complete list of alerts and their meaning, see *Alerts* on page *104*.

NETWORK CONNECTIVITY PROBLEMS

To establish full network connectivity with the programmer, step-by-step instructions are found under *Power On the Programmer* on page *70*.

If you are already logged in to the programmer and have lost network connectivity, first log off to return to the login screen: return to the Start screen (see *Start Screen* on page 74) and touch the circle-X (exit) button at upper right, and then select **EXIT** on the **PROGRAMMER EXIT** dialog. Follow the instructions under *Log In to the PDMS on the RNS Programmer* on page *75* to establish a connection.

- If a PDMS screen appears to get “stuck” or is not responding, select the **REFRESH** button at upper right.

  Note: *If you attempt to connect to a Wi-Fi network that requires you to go to an Internet website to log in, as in some hotels and coffee shops, you will not be able to log in because the programmer does not have an Internet browser program. As a medical device, its Internet connectivity is restricted to the PDMS only.*

ABNORMAL LEAD IMPEDANCE (>3500 OHMS OR <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.
   - Disconnect and reconnect the leads to the connector cover and neurostimulator according to the instructions in the relevant section of the system manual.
   - View the live ECoGs to verify that the signal is sufficient and without noise or artifacts.
   - 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.
    - Disconnect leads, place leads in the opposite connector cover ports, and reconnect the connector cover and neurostimulator according to the instructions in the relevant section of the system manual.
    - Program the new lead information and montage and use the same electrode labels for the new lead configuration.
    - View the live ECoGs to verify that the signal is sufficient and without noise or artifacts.
    - 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 the instructions in the relevant section of the system manual.

    Depth lead - Impedance < 250 Ohms

    - The depth lead may be damaged and should be replaced. Refer to the instructions in the relevant section of the system manual.

    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 the instructions in the relevant section of the system manual.

    Cortical strip lead - Impedance < 250 Ohms

    - The cortical strip lead may be damaged and should be replaced. Refer to the instructions in the relevant section of the system manual.

    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.
    - Disconnect the leads from the connector cover and reconnect the leads to a new connector cover. Connect to the neurostimulator and troubleshoot according to the instructions in the relevant section of the system manual.
    - View the live ECoGs to verify that the signal is sufficient and without noise or artifacts.
    - Repeat impedance measurements.
7. If the impedance remains abnormal, replace the neurostimulator. Refer to the instructions in the relevant section of the system manual.

TROUBLESHOOTING DURING A ROUTINE FOLLOW-UP

1. Repeat lead impedance measurements to verify abnormal lead impedance.
2. Take an image (X-ray or CT scan) of the implanted lead(s) and connector cover to discern the integrity of the lead.
    - **Lead Damage** – If the lead is damaged or fractured, it is recommended to abandon and replace the lead. Refer to the instructions in the relevant section of the system manual.
    - **Poor Connection** – If the lead is not completely installed in the connector cover, it is recommended to surgically revise the connection between the connector cover and lead. Refer to the instructions in the relevant section of the system manual.

    Note: *It is normal for lead impedance measurements to fluctuate following the implant procedure due to the acute injury and healing processes of the brain tissue.*

    Note: *Lead damage may not be immediately apparent from the live ECoGs. Using the* ***NOISE*** *ECoG capture trigger may be helpful in future troubleshooting techniques.*

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 (see *Figure 84* on page *83* and *Figure 85* on page *84*) 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 neurostimulator configuration settings to determine the cause. An example interrogation report is shown below.

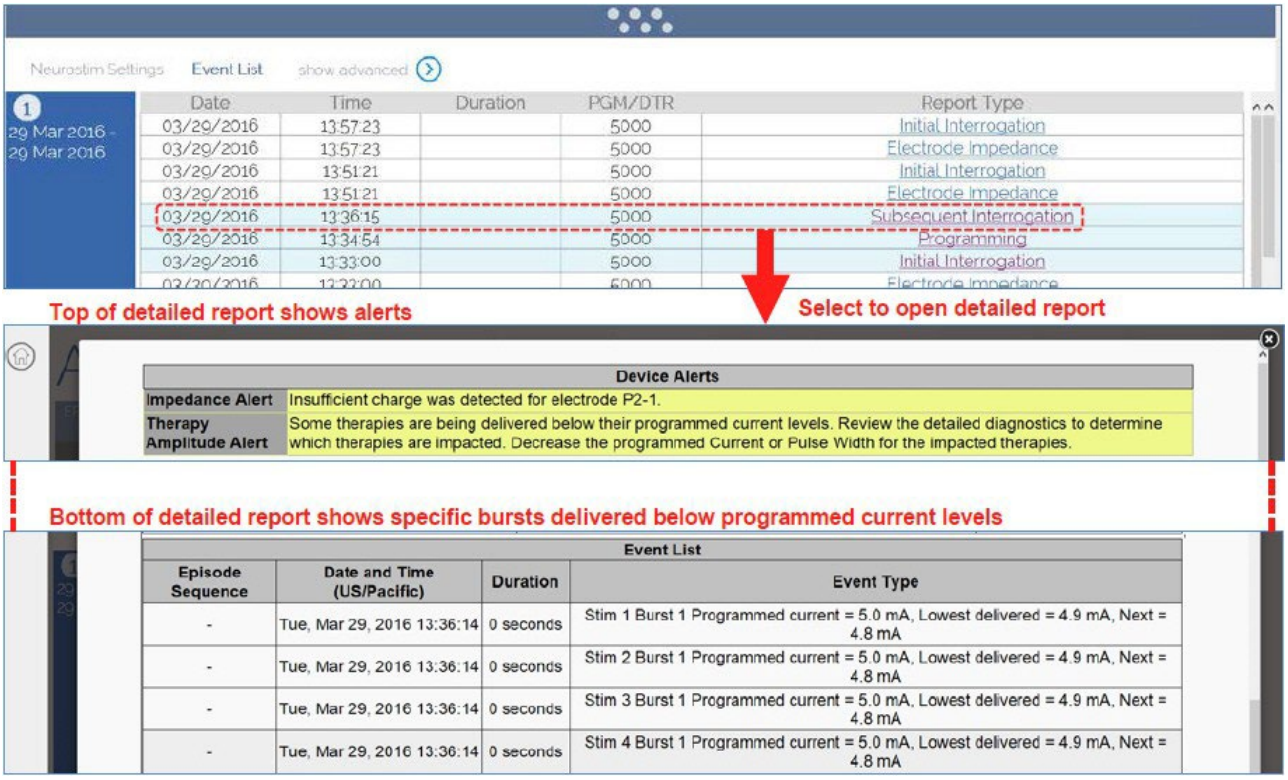


Figure 116 Accessing an interrogation report that shows insufficient charge

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 the recording montage has 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 Neurostimulator, move them away from the neurostimulator.
4. Remove the connector cover from the RNS Neurostimulator using the torque driver.
5. Flush the connector cover (with leads inserted) and the RNS 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 Neurostimulator. Verify, once again, that the leads are fully inserted in the connector cover ports.
9. Secure the connector cover onto the RNS 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) / static electricity shocks to the programmer.
11. If the signal contains noise or artifacts, disconnect the AC adapter from the programmer and run on battery power. (Make sure the battery is charged before doing so.) 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 the relevant section of the system manual.
13. If impedance measurements are normal, but the problem remains, try using a different programmer, if available.
14. If the problem persists, replace the neurostimulator. Refer to the relevant section of the system manual.

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 for *Poor or No Communication Between the RNS Neurostimulator and the Programmer* on page *112* in this section.
3. If the signal is not sufficient, measure the impedances. If the impedances are out of range, follow the instructions in the relevant section of the system manual.

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 programmer.
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 programmer 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.)
    - Reposition the wand over the neurostimulator and interrogate.
    - 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 programmer. Attempt the interrogation again.
6. Try a different programmer, if available.
    - Try interrogating a different neurostimulator, if available, to see if the problem is with the neurostimulator.

PROGRAMMER DOES NOT TURN ON

1. Charge the programmer for at least four (4) hours.
2. Press and hold the power button for four (4) seconds. After 2-3 seconds, activity begins on screen, which indicates it is powering on. If the programmer does not turn on, follow these instructions again. If the programmer still does not turn on, contact NeuroPace for further assistance (see *Contact NeuroPace* on back page).

PROGRAMMER FREEZES OR DOES NOT TURN OFF

1. Plug the programmer into a grounded power outlet.
2. Shut down the programmer: Press and hold the power button until a white screen appears from the top. That screen has an arrow pointing downward and shows the text "You or anyone else using this PC will lose unsaved work. Slide to shut down your PC." Then slide down and shut down the programmer.
3. Restart the programmer: Press and hold down the power button for about four (4) seconds. After 2-3 seconds, the screen shows activity, which indicates it is powering on. If the programmer does not restart, follow these instructions again. If the programmer still does not start, contact NeuroPace for further assistance (see *Contact NeuroPace* on back page).

PROGRAMMER SHUTS DOWN

1. Plug the programmer into a grounded power outlet.
2. Restart the programmer: Press and hold the programmer power button. After 2-3 seconds, activity begins on screen, which indicates it is powering on. If the programmer does not power on, follow these instructions again. If the programmer still does not power on, contact NeuroPace for further assistance (see *Contact NeuroPace* on back page).

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 measure impedance or test stimulation (test therapy).

POSSIBLE CAUSE

- The neurostimulator may be delivering therapy. The system cannot measure impedance or test stimulation during therapy delivery.
- The neurostimulator may be detecting an episode. The system cannot measure impedance or test stimulation during episode detection.

ACTIONS TO BE TAKEN

1. Wait until therapy delivery completes or temporarily disable therapy delivery.
2. Wait until episode detection completes or temporarily disable detection.

NEUROPACE UPDATE CENTER

If upon logging into the programmer, new Application software updates are available for installation, the **NEUROPACE UPDATE CENTER** will open. As described below, the Update Center identifies the Application software type(s) and allows for selection of a convenient time to perform the updates.

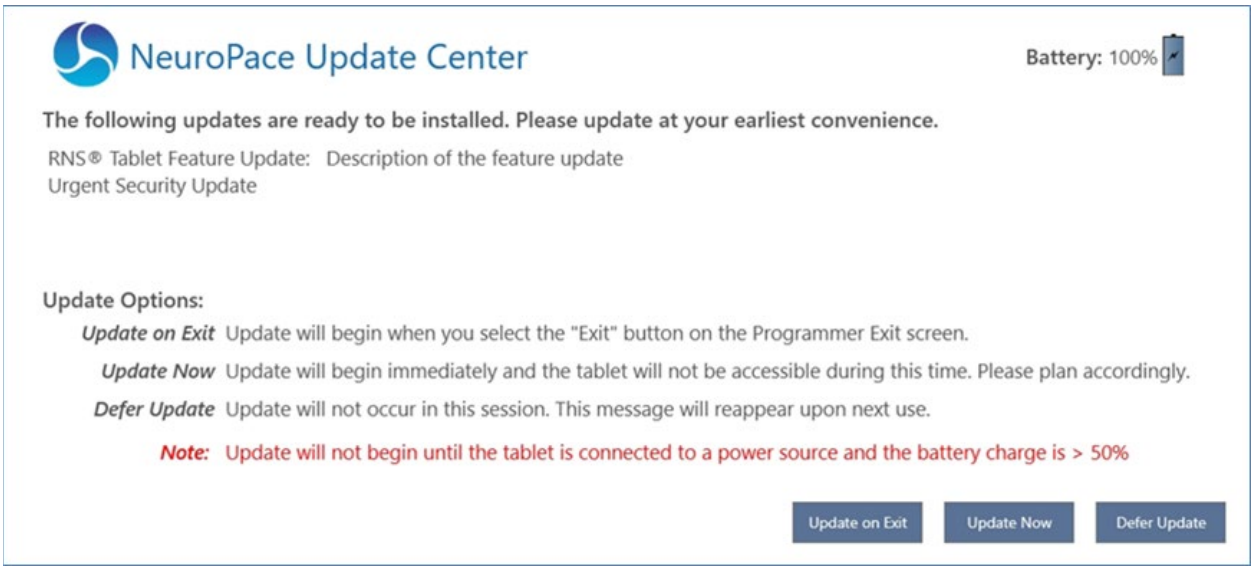


Figure 117 NeuroPace Update Center

There are two types of updates:

1. **RNS Programmer Feature Update:** These updates contain RNS Programmer interface changes or new feature updates. A description of the feature update is provided with further information.
2. **Urgent Security Update:** These updates are required to ensure cybersecurity for the RNS Programmer and should be performed as soon as possible. These updates do not include any RNS Programmer interface changes or new features.

   Note: *Some updates require the programmer to restart. Under these circumstances, upon completion of the update, the system will restart automatically and will require log in to be performed again.*

It is important to install updates; however, the time it takes for an update to complete can vary from less than a minute to up to an hour. Accordingly, be sure to perform an update when there is adequate time. Once an update starts it cannot be cancelled; interrupting an update by powering off the programmer can render the programmer unusable.

There are three options available to manage updates:

1. **UPDATE ON EXIT**: This option postpones the update until **EXIT** is selected on the RNS Programmer Exit dialog. To maintain programmer availability within the next hour (such as for a patient clinic visit), NeuroPace recommends selecting **UPDATE ON EXIT**.
2. **UPDATE NOW**: This **OPTION** starts the update immediately and the RNS Programmer will not be available during this time. Do not use this option if the RNS Programmer is required for use within the next hour.

3. **DEFER UPDATE**: This option postpones the update until the next use of the RNS Programmer, at which time the **NEUROPACE UPDATE CENTER** will appear again.

UPDATE PROCESS AND POWER REQUIREMENTS

When an update begins, the screen name shows **NEUROPACE UPDATE CENTER: INSTALLING UPDATE(S)** and reports update progress.

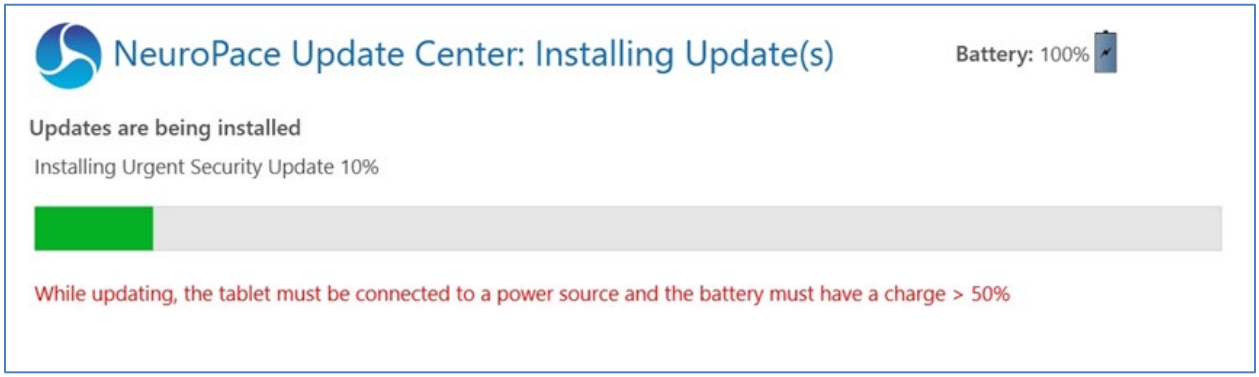


Figure 118 Installing Updates Progress

POWER REQUIREMENTS

Updates cannot proceed until the programmer is connected to a power source and the battery charge is greater than 50%. If the power requirements are not met, instructions to address the unmet power requirements will be displayed and the progress status bar will not commence (see figure below). Follow the instructions on screen as applicable to either plug in the programmer or wait for the battery to reach the required level. When the power requirements are met, the update will begin automatically.

These power requirements ensure that the RNS Programmer remains powered on throughout the update, so the update is not interrupted. It is recommended to keep the programmer plugged in until the update completes.

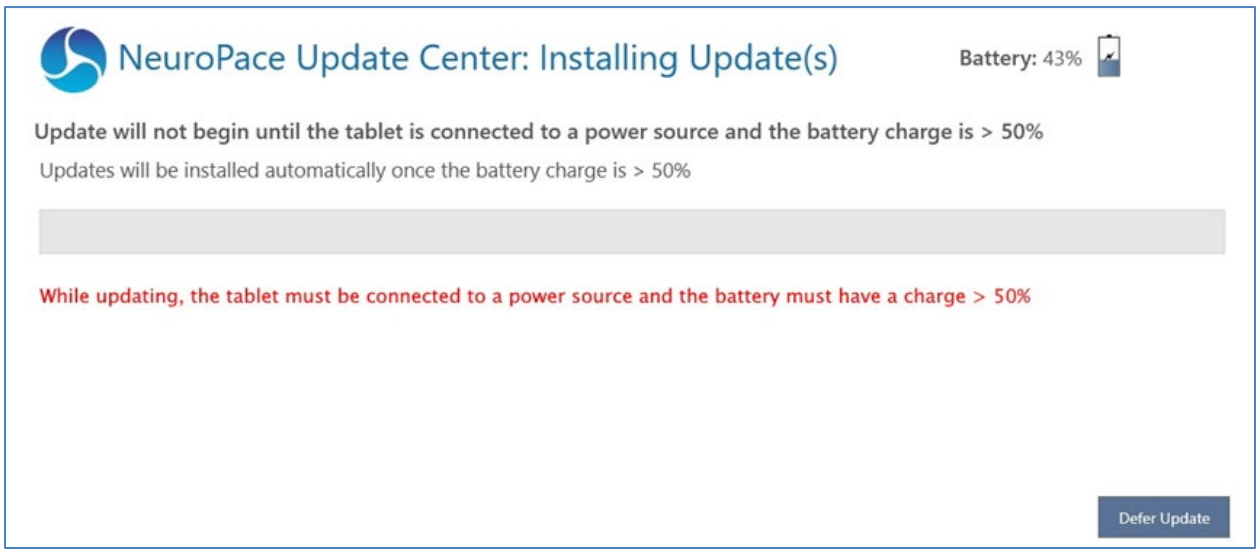


Figure 119 Power requirements must be met before updates will commence

If the power requirements are not met, and the update has not begun, select the option to **DEFER UPDATE**. At future power on and log in, the **NEUROPACE UPDATE CENTER** will appear again.

CYBERSECURITY

To protect the RNS System, which includes the PDMS and the programmer, NeuroPace undertakes a systematic and environmental use approach to ensuring safety, privacy, and security. NeuroPace has implemented a cybersecurity program that includes strong authentication practices, access management processes, deployed data encryption, installed endpoint protection, centralized patch updating, and other cybersecurity practices to secure patient information. Periodically, NeuroPace may update this information with important information related to the RNS System.

Access to the PDMS and the programmer is restricted to authorized healthcare professionals with assigned user credentials. NeuroPace personnel are granted access to PDMS accounts via unique usernames and passwords to each programmer and/or PDMS instance. NeuroPace maintenance accounts are designated for NeuroPace Field Clinical Engineers to provide technical support and maintenance to healthcare providers using the RNS System. No additional user accounts exist, and access privileges cannot be created or modified without explicit approval from NeuroPace system administrators.

To ensure the security of patient data and communications, and to prevent unauthorized access to programming functions, PDMS and the programmer incorporate the following security controls:

- Password protection is required to access the programmer.
- Access to the PDMS requires a unique user account, issued only after successful completion of appropriate training.
- Passwords must meet industry-standard complexity requirements and are subject to periodic expiration and updates.
- Accounts are automatically locked after multiple failed login attempts.
- Inactive user sessions are automatically logged off after a predetermined period.
- Interrogated data is automatically transferred from the programmer to the PDMS upon a successful internet connection.
- Once data is successfully transferred, it is deleted from the programmer to prevent local retention.
- All data is encrypted both at rest and in transit using industry-standard encryption protocols.
- The programmer is restricted from downloading or installing any unauthorized applications or software.
- NeuroPace managed anti-virus protection is deployed on each programmer.

NeuroPace manages data backups to ensure integrity and availability of patient information. Additionally, users are expected to follow these cybersecurity best practices when using the PDMS and the programmer:

- Never share your PDMS or physician programmer username and password.
- Do not permit others to access your PDMS account or use the programmer.
- Connect the programmer only to secure, trusted networks.
- Promptly install all software updates released for the programmer as they become available.
- When not in use, store the programmer in a locked and secure location.
- If device is lost or stolen, immediately notify NeuroPace at productmonitoring@neuropace.com

PRIVACY AND LEGAL

PRIVACY AND LEGAL NOTICE

NeuroPace is committed to protecting the privacy of our customers and patients. This privacy statement summarizes how we protect, gather, and use personal information of users. For more information, view Privacy Policies online at *https://www.neuropace.com/privacy/*.

For important legal information regarding the use of NeuroPace products, services, and intellectual property, please refer to our Legal Notice, available at: *https://www.neuropace.com/legal/*. This notice contains terms and conditions that govern your access to and use of NeuroPace materials.

FCC INFORMATION

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

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

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

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

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

TECHNICAL SPECIFICATIONS

PROGRAMMER

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	5V, 500 mA
Operating Temperature	0 °C to 40 °C

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

WAND (MODEL W-02)

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
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

PROGRAMMER WIRELESS

WIRELESS FUNCTION	Transfer data between the Neurostimulator and the Patient Data Management System (PDMS)
WIRELESS TECHNOLOGY TYPE	Wi-Fi dual band 802.11n and 802.11ac 4G (fallback to 3G)
OPERATING DISTANCE	Varies - Wi-Fi and cellular range similar to other smartphones and programmers
FREQUENCY BAND OF OPERATION	Wi-Fi: 2.4 GHz or 5 GHz Cellular: 700, 1900, 1700, 2100 MHz
INTENDED USE ENVIRONMENT	Clinical setting only
REQUIRED WIRELESS QUALITY OF SERVICE	The requirements for quality of service vary depending on the clinical function. The programmer login screen displays the network status indicator on the lower right hand corner of the screen. The indicator is a signal strength symbol consistent with commercial programmer computers. There are no requirements for timely data transmission. The programmer locally stores data until a connection to PDMS is available. Data are resent until they are successfully received.
RECOMMENDED WIRELESS SECURITY	Wi-Fi: WPA2

RNS® SYSTEM WIRELESS

WIRELESS FUNCTION	Transfer data between the neurostimulator and the programmer 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

PROGRAMMER WI-FI SPECIFICATIONS

Table 1 Wi-Fi Specifications Dell Model 5285 and 5290 Model: T17G Reg Type No: T17G001 and T17G002 FCC ID N7NEM7455-D7	
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 GHz
Class:	NII
Modulation:	OFDM
Effective Radiated Power:	13.96 dBm
Table 2 Wi-Fi Specifications Dell Model 7200 Model: T04J Reg Type No: T04J001 FCC ID MCL T77W968-D2	
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 GHz
Class:	NII
Modulation:	OFDM
Effective Radiated Power:	14.15 dBm
Table 3 Wi-Fi Specifications Model: Dell 7320 Contains FCC ID MCLT77W968-D10 Contains FCC ID PD9AX201D2	
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 GHz
Class:	NII
Modulation:	OFDM
Effective Radiated Power:	24.24 dBm
Table 4 Wi-Fi Specifications Model: Dell 7350 Contains FCC ID: E2K BE200D2 Contains FCC ID: E2K T99W373PC15	
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 GHz

Class:	NII
Modulation:	OFDM
Effective Radiated Power:	28.46 dBm

STERILIZATION AND STORAGE

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® 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 programmer may be sensitive to electrostatic discharge / static electricity. Handle the programmer ports carefully. If exposed to electrostatic discharge, the programmer may experience telemetry artifacts or errors, or may freeze. In the event of a programmer freeze, refer to *Programmer Freezes or Does Not Turn Off* on page *113*.

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 *112*. 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 *10* 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:

- 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 *Contact NeuroPace* on back page). If a patient suspects EMI is disrupting the operations 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 (Programmer), model 5000
- Wand, model W-02
- Remote Monitor, models 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 device.
- 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 6 Guidance and manufacturer's declaration – electromagnetic emissions – for all equipment and systems

Emissions test	Compliance	Electromagnetic environment – guidance
Conducted emissions (CISPR 11)	Class B, Group 1150 kHz to 30 MHz	The RNS System uses RF energy only for its internal function. Nearby electronic equipment may be affected.
RF emissions (CISPR 11)	Class B, Group 1 30 MHz to 6 GHz	
Harmonic emissions (IEC 61000-3-2)	Class A Device[1]	The RNS System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions (IEC 61000-3-3)	Limits per Clause 5 of the Standard	

[1] Programmer (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 7 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[1] ± 2, 4, 8, 15 kV air discharge[1]	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst (IEC 61000-4-4)	± 2 kV for power supply lines[2]	Mains power quality should be that of a typical commercial or hospital environment.
Surge (IEC 61000-4-5)	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth[3]	
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)	0% U_T 0.5 cycle 0% U_T 1 cycle[4] 40% U_T 5 cycles[4] 70% U_T 25 cycles 0% U_T 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[5]	

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

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

[3] Immunity to surge line to earth tested with Remote Monitor (model 5106).

[4] Immunity to voltage dips with compliance to 0% U_T 1 cycle for Programmer (model 5000) and Remote Monitor (models 5100, 5106).

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

Table 8 Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems that are not life supporting

Immunity Test	Compliance Level	Electromagnetic environment – guidance
Conducted RF (IEC 61000-4-6)	3 Vrms 150 KHz to 80 MHz 6 Vrms ISM Bands[1] 6 Vrms Amateur bands	Portable and mobile RF communications equipment should be used no closer to any part of the RNS System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance[2]** d = 1.17√P (80 MHz to 800MHz) d = 2.33√P (800 MHz to 2.7 GHz) Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[3], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated Immunity (IEC 61000-4-3)	10 V/m 80 MHz to 2.7 GHz[4]	
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)[5]	See next table below footnotes.	
Proximity magnetic fields (IEC 61000-4-39)[6]	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	

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

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

[3] 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.

[4] Radiated immunity of the Programmer (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.

[5] Proximity fields from RF wireless communications equipment tested with Remote Monitor (model 5106)

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

Table 9 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 10 Recommended separation distances between portable and mobile RF communications equipment and the RNS System[1, 2]			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz $d = 1.17\sqrt{P}$**	**800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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

[2] 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.

SYMBOLS

Explanation of symbols on product or package labeling

Caution

Do Not Resterilize

MR Conditional

MR Unsafe

Prescription Only

Non-Pyrogenic

Single Use

Sterilized Using Ethylene Oxide

Temperature limits during use

Use

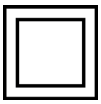
Temperature limits during storage or transport

Storage

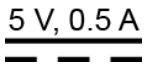
Manufacturer

Serial number

Type BF applied part



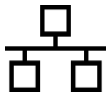
Class II electrical protection



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.

APPENDIX A: DATA SUPPORTING THE ECOG ASSISTANT AI ALGORITHM

ECoG Assistant is a user-enabled feature within the Patient Data Management System (PDMS) software. Its application is to classify ***intracranial*** EEG (iEEG) records as either likely to contain or not likely to contain ECoGs of Interest, using a static AI-developed algorithm, to assist clinicians with their manual review and analysis of patient iEEG data.

Note that ECoG records, including Long Episode ECoG records, should be reviewed by a clinician. Note the following disclaimer text displayed on the top center of the ECoG Library Screen and the bottom center of the ECoG Assistant Trends Report within the PDMS user interface:

> *"ECoG Assistant is a tool for identifying ECoGs of Interest and does not replace clinical review and judgment. ECoG Assistant was developed on long episode, magnet, and saturation ECoGs, and excludes scheduled and user-saved ECoGs."*

See the section *ECoG Assistant Functionality* on page *22* and *Review ECoG Assistant Trends* on page *24* for ECoG Assistant feature operation.

DEVELOPMENT

The ECoG Assistant algorithm model was developed on a static set of iEEG long episode records using deep learning-based techniques. The dataset included patients who were previously or are currently enrolled in NeuroPace RNS System feasibility, pivotal, and long-term treatment trials.

Model development was conducted using a static dataset of 124,450 expert-labeled iEEG long episode records from 113 patients included in the PDMS database. The model was built using a full static dataset (training, tuning, and testing) of 304,472 channels stemming from the 124,450 records. The demographics of this dataset are outlined in the table below. Ethnicity was not collected in this dataset.

Table 11 ECoG Assistant Development Dataset Demographics

Demographic	Category	Number of Patients
Age	18 - 22 yrs. old	22
	23 - 50 yrs. old	80
	>50 yrs. old	11
Sex	Male	59
	Female	54

PERFORMANCE

PRIMARY REFERENCE STANDARD

The ECoG Assistant algorithm performance testing was completed using a primary reference standard dataset from patients who were previously or are currently enrolled in NeuroPace RNS System pivotal, feasibility, long-term treatment (LTT), and post-approval (PAS) study trials. This dataset consisted of 778 expert-labeled iEEG long episode records from 100 patients.

The Primary Reference Standard was established by a panel of three board-certified epileptologists labeling iEEG records stored by the RNS System, where all 3 labelers agreed on classification as seizure vs. non-seizure.

DEVELOPMENT OF THE PRIMARY REFERENCE STANDARD

The Primary Reference Standard represents the 83.2% of records in the Primary Expert-Labeled Dataset which had full consensus from all three expert labelers. The Primary Expert-Labeled dataset was selected randomly from patients with focal epilepsy who had participated in NeuroPace clinical trials, excluding patients whose data had been used for development (training, validation, and test datasets), described as follows.

1. 100 patients were randomly selected from the master RNS System database (Patient Database Management System, or PDMS). The selection query excluded patients whose data were used in any way for development of the algorithm. Of these 100 patients, 50 patients were drawn from Post-Approval Study (PAS) patients, which was a more recent focal epilepsy trial, and 50 patients were drawn from patients in previous clinical trials in focal epilepsy (Feasibility, Pivotal, and Long-Term Treatment) in order to balance between newer and older datasets. No ordering or sorting was applied at the patient selection level except for these constraints.
2. For each selected patient, 8-9 (mean 8.8 per patient) Long Episode records were drawn completely at random from their available Long Episode records, yielding 880 total records. Additionally, 2-3 (mean 2.2 per patient) Long Episode Records were drawn at random from those previously identified as likely to contain electrographic seizures by the algorithm of Barry et al. (2021), yielding 220 total additional records, for a grand total of 1100 records. Selections were drawn from the master RNS System database (PDMS). No ordering, sorting, readability analysis, or other enrichment was applied, other than the filtering for Long Episode trigger type, and the selection of 20% of total records from those likely to contain electrographic seizures. Records from a patient's entire treatment history were equally eligible for selection.
3. Three reviewers (board-certified epileptologists, trained and practicing at different institutions) were then instructed to label 1000 of these records. Bias or subjectivity in labeling were minimized by using criteria aligned with the American Clinical Neurophysiology Society (ACNS) definition of an electrographic seizure as an abnormal, paroxysmal EEG event that evolves over time in frequency, morphology, or location, lasting at least 10 seconds. The three reviewers completed labeling 982, 997, and 1068 records respectively, yielding 978 which were labeled by all three reviewers. Each record could contain up to four intracranial EEG (iEEG) channels, and if any channel was labeled as a seizure, the entire record was considered a seizure for that reviewer.

   Note: for purpose of performance analysis, an "unsure" label was treated as "electrographic seizure". Only 21 records (2.2% of the Primary Expert-Labeled Dataset) had an "unsure" label applied by any reviewer. No record had an "unsure" label applied by more than one reviewer.

4. After labeling, patients represented by more than 10 total records were reduced to 10 records by excluding completely at random. For instance, if a patient was represented by 9 or 10 records, no change would be made, but if a patient was represented by 11 records, one record would be excluded completely at random. This step yielded 935 records in the Primary Expert-Labeled Dataset.
5. Finally, consensus was determined by identifying records where all three experts assigned the same label, either “seizure” or “non-seizure.” These records – 778 of 935, or 83.2% – formed the Primary Reference Standard.

Note that the filtering for Long Episode trigger type, the selection of 20% of total records from those “likely to contain electrographic seizures” by the Barry et al. (2021) algorithm, and reduction of the number of records from 1100 to 1000, then to 978, then 935, then to 778, may have introduced bias in the performance evaluation.

Performance of ECoG Assistant against the Primary Reference Standard

The demographics of the Primary Reference Standard dataset, where the three expert reviewers agreed, are outlined in *Table 12* below.

Table 12 ECoG Assistant Performance Dataset Demographics

Demographic	Category	Number of Patients
Age*	18 - 22 yrs. old	12
	23 - 50 yrs. old	78
	>50 yrs. old	30
Sex	Male	47
	Female	53
Ethnicity	Native American	1
	Asian	3
	Black	4
	Hispanic	5
	White	36
	Not Specified	51

*Note: The total of patient counts shown across the ‘Age’ categories is greater than 100. Ages were determined at the time the iEEG record was stored. Patients may have records in more than one age category.

The ECoG Assistant algorithm performed with 93% sensitivity against the Primary Reference Standard. Details are shown in *Table 13* below, including record numbers and clustered-bootstrap 95% confidence intervals (CIs).

Table 13 Performance on Primary Reference Standard (Consensus Records Only)

Quantity	Value
# Patients	100
# Records	778
Sensitivity	0.93 (448/480) (95% CI 0.89 - 0.96)

Sensitivity is the proportion of records correctly identified by ECoG Assistant as likely to contain electrographic seizures, out of the total number of iEEG long episode records in the Primary Reference Standard labeled by all 3 board-certified epileptologists as containing electrographic seizures.

EXCLUSION OF RECORDS FROM PRIMARY REFERENCE STANDARD

Long episode records in which the three board-certified epileptologist labelers did not reach unanimous agreement on the seizure vs. non-seizure classification ("non-consensus records") were excluded from the Primary Reference Standard (PRS) performance analysis.

However, an exploratory analysis was performed using this subset of 157 non-consensus long episode records for which the three expert reviewers did not agree. Results of this analysis are shown in Table 14 below.

Table 14 Supplementary Analysis on Non-Consensus Records

Subset	Expert review outcome	Number of records	Records classified as likely electrographic seizure by ECoG Assistant	
			Number	Percent (95% CI)
A	2/3 experts: Seizure 1/3 experts: Non-seizure	54	25	46.3% (33.7–59.4%)
B	1/3 experts: Seizure 2/3 experts: Non-seizure	103	14	13.6% (8.3–21.5%)

Note that the clinical impact of using this algorithm to assist in changing device parameters has not been evaluated and is currently unknown. Furthermore, the primary clinical reference standard was established by 3/3 expert consensus of true electrographic seizures. For these reasons, using this assistive tool to guide adjustment of detection or stimulation parameters may affect device safety and effectiveness.

GLOSSARY

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 iEEG signal.

Asynchronous Pulse
Delivery of the first pulse in a burst independent of the iEEG 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 $\mu C/cm^2$/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 iEEG 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 Cortical Strip Lead lies on the surface of the brain (cortex) and can detect the electrical activity of the brain and deliver stimulation.

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.

iEEG (ECoG)
Intracranial electroencephalograph (iEEG), also referred to herein as electrocorticogram (ECoG). Electrical activity derived directly from the cerebral cortex. Also used to describe the neurostimulator or programmer stored record of this activity (for example, “ECoG record” or “intracranial EEG record”).

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

ECoG (iEEG) Trigger
The type of neurostimulator activity selected by the user to result in the capture of an ECoG (iEEG) 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
iEEG 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 (iEEG) 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 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 ECoGs 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.

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 intracranial EEG 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 intracranial EEG signal.

Technical Parameters
Option to configure detection using all detection parameters.

Telemetry
Communication between the neurostimulator and the programmer.

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