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Clinician Programmer Application for Deep Brain Stimulation

A610

Clinician Programming Guide for

Model B35200 and Model B35300 Percept™ neurostimulators with BrainSense™ technology and Adaptive Therapy

Application version 5.0

! USA Rx only

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Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

For USA audiences only

Manufacturer

Authorized Representative in the European Community

Importer

Medical device

Consult instructions for use

Magnetic Resonance (MR) Unsafe

Model number

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Information available for the Deep Brain Stimulation Therapies:

The information for prescribers manual provides information about contraindications, warnings, precautions, adverse events, sterilization, and component disposal. The information for prescribers addendums contain indication-specific information. For customers in Japan, the appropriate package insert provides information about safety, contraindications, warnings, precautions, and adverse events.

The indications sheet provides information about indications and related information. For customers in Japan, the appropriate package insert provides information about indications.

The system eligibility and battery longevity manual describes programming considerations and provides battery longevity information to aid in the appropriate neurostimulator selection.

MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neurostimulation system.

Product manuals, such as programming guides, recharging guides, and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.

! USA The clinical summary provides information about the clinical study results for the neurostimulation system.

Refer to the literature provided by the clinician tablet manufacturer for information regarding wireless use.

Refer to the Communicator technical manual for warnings, precautions, device description, package contents, device specifications, instructions for use, and maintenance information.

DESCRIPTION OF THE PROGRAMMING SYSTEM

Model A610 Clinician Programmer Application

The Model A610 Clinician Programmer Application for Deep Brain Stimulation (DBS) provides the user interface for clinicians to configure stimulation and obtain diagnostic information from an implantable or external neurostimulator. In addition, the application facilitates implant and replacement procedures and generates reports. The clinician programmer application software runs on a non-medical device (a Medtronic supplied commercially available tablet).

This programming guide is for use with the following implantable neurostimulators (INS):

- Model B35200 Percept™ PC
- Model B35300 Percept RC

Intended purpose

The clinician programmer application is intended for use by clinicians in the programming of Medtronic neurostimulators for deep brain stimulation.

Compatibility

Note: Previous application versions may not be compatible with all models.

The Model A610 Clinician Programmer Application is compatible with the following neurostimulator and lead models:

Implantable neurostimulators (INS):

- Model B35200 Percept PC
- Model B35300 Percept RC
- Model 37601 Activa™ PC[1]
- Model 37602 Activa SC[1]
- Model 37603 Activa SC[1]
- Model 37612 Activa RC[1]

External neurostimulators (ENS):

- Model 37022[1]

1x4 leads:

- Models 3387, 3387S, 3389, 3389S
- Models 3391, 3391S

SenSight™ directional leads:

- Models B33005, B33015

[1] Programming information for the Activa implantable neurostimulators and Model 37022 external neurostimulator, which the Model A610 Clinician Programmer Application is also intended to program, can be found in a separate programming manual.

Other components of the programming system

Clinician Tablet

The clinician tablet, with Android™*-based operating system, is intended for use by clinicians to use in conjunction with the clinician programmer app to program Medtronic neurostimulators.

Model 8880T2 Communicator

The Model 8880T2 Communicator is intended for use by clinicians to use in conjunction with the clinician tablet and clinician programmer app for communication with Medtronic Neuromodulation therapy devices.

Refer to the Model 8880T2 Communicator Technical Manual for specifications and instructions for use.

Model A901 Communication Manager Application

The Model A901 Communication Manager Application is intended to manage the telemetry communications for the clinician tablet.

Model A902 Patient Data Service Application

The Model A902 Patient Data Service Application is intended for use by clinicians to access reports for all patients whose Medtronic devices have been programmed using the clinician programmer app on the clinician tablet.

Refer to "Patient Data Service app", page 64 for instructions on using the Patient Data Service app.

Model A90400 SureTune™ Software Connector Application

The Model A90400 SureTune™ software Connector Application is an optional Medtronic designed, Android application that is installed on the clinician tablet. This app allows clinicians to connect to a remote server and import patient-specific anatomic shapes and lead data from the SureTune software to the clinician programmer app. Refer to "ANATOMY DATA", page 57 for more information.

PROGRAMMER SETUP

Note: In this manual, figures of the app screens are representative. What is displayed on the actual screens may differ.

Finding and opening the app

1. Navigate to the Apps on the clinician tablet.
2. Find the DBS app icon.
3. Tap the DBS app icon to open the app.

Notes:

- Do not leave the clinician tablet unattended during an active programming session.
- Information may be lost if the application is improperly terminated during a programming session.
- End the session properly by navigating to the **HOME** screen and completing the **END SESSION** workflow. For more information, see "ENDING A SESSION", page 58.

Preparing the clinician tablet

Check the battery level of the tablet:

- The tablet's battery level is shown on the tablet status bar uppermost row of indicators on the tablet screen).
- Recharge the tablet if the battery level is low.

Data security

The clinician programmer system uses and stores data about the patient's health and implanted medical device. This data is protected by application-level controls and encryption provided by the clinician tablet. The clinician programmer system does not provide data protection for data exported to another destination. Exported data should be handled in accordance with your facility's security policy for data handling and storage.

- Medtronic recommends that you always save exported data to the default reports location on the clinician tablet.

Network connectivity

Network connectivity is required for initial app registration and for installation of Medtronic app updates and firmware updates. Network connectivity is not required for neurostimulator programming unless anatomy data import is desired. To protect your clinician programmer system, Medtronic recommends you implement the following security measures:

- Consider securing your tablet by disabling network connectivity during programming sessions.
- Use a managed, trusted Wi-Fi® connection when network connectivity is needed.
- Connect the clinician tablet to the network monthly to check for notifications on available updates. To avoid delays in programming, plan for updates accordingly.

Note: Connecting the clinician tablet to a network that includes other equipment could result in unforeseen risks to patients, operators, or third parties. Changes to your network such as adding, disconnecting, and upgrading equipment; upgrading or installing software; or changing network configurations could also introduce additional risks. Analyze, evaluate, and control any identified risks.

If you suspect a cybersecurity event has occurred, stop using the app (if possible) and contact Medtronic using the contact information listed on the back cover of this manual. Medtronic will document the cybersecurity event, analyze the event, and recommend actionable items appropriate for the event in a timely manner.

If your clinician tablet is lost or stolen, contact Medtronic using the contact information listed on the back cover of this manual.

If more details are needed about the system, software, hardware, or firmware (such as a Software Bill of Materials), contact Medtronic.

Installing and updating application

For assistance with downloading, registering, or installing the application, contact Medtronic using the information on the back cover of this manual. In the U.S., call 1-800-707-0933 for Medtronic Technical Services.

Medtronic periodically updates the therapy app and will not install updates without notifying the user. Network connectivity is required to update the app. When notified that an app update is available, follow the instructions provided by Medtronic to install the update and remain connected to the network until the update successfully installs. Confirm the correct software version in the **ABOUT** screen.

Installing communicator updates

When notified to install a communicator firmware update, connect the communicator to the clinician tablet using the USB connector cable. Follow the instructions provided by Medtronic to install the update.

Installing neurostimulator updates

When a neurostimulator requires a firmware update, you will be notified after the communicator has connected with the neurostimulator. The screen displays the message **NEUROSTIMULATOR UPDATING**. Follow the on-screen instructions to install the update.

The neurostimulator firmware update is a two-step process. Step 1 updates the neurostimulator, and Step 2 restarts the neurostimulator to activate the new firmware. You will be prompted to initiate this restart, select **RESTART** to begin. During the restart, therapy is interrupted for less than 30 seconds. The patient may experience temporary discomfort. Stimulation automatically resumes once the restart is complete. All therapy parameters will be retained.

When the neurostimulator restart is complete, you will be directed to the HOME screen, and a banner will display **INFORMATION: NEUROSTIMULATOR UPDATE SUCCESSFUL** at the bottom of the screen.

For Percept RC ONLY: To perform a neurostimulator firmware update, the neurostimulator battery must have a charge level of 70% or greater. If the neurostimulator battery level is below 70%, you may continue with the programming session without updating the firmware. In this case, ask the patient to come to their next appointment with a fully-charged neurostimulator battery.

Returning the clinician tablet

If you need to return the clinician tablet for disposal or replacement, contact Medtronic using the contact information listed on the back cover of this manual. Instructions will be provided for preparing the clinician tablet for return.

DEMO MODE

You can use Demo Mode to explore the clinician programmer app without interrogating or updating a neurostimulator.

When the app is in Demo Mode, it is not communicating with a real neurostimulator and does not require the use of a communicator. Any data displayed in Demo Mode are not actual.

Demo Mode can be used for training and demonstration purposes and to familiarize yourself with the app interface before starting an actual programming session.

Using Demo Mode

1. After opening the app, tap **DEMO**.
2. Use the options available to select the parameters to be used in Demo Mode.
3. On the **HOME** screen, check that **DEMO** appears in orange letters at the top of the screen.
4. To exit Demo Mode, tap the **End session** (button and end the Demo Mode session.

BUTTONS AND ICONS

Buttons and icons that are specific to a task or screen are defined within the corresponding section of the manual.

See Table 1 for definitions of buttons and icons that appear throughout the clinician programmer app.

Table 1. Definitions of buttons and icons

Button or icon	Definition
	Stimulation toggle – Tap this button to turn stimulation on or off. Green indicates stimulation is on.
	Menu button – Tap this button to access a menu with additional features.
	Back button – Tap this button to return to the previous screen.
	Home button – Tap this button to return to the **HOME** screen.
	End session button – Tap this button to end a programming session.
	Settings button – Tap this button to access additional options.
	Sensing icon – Indicates a program that is configured for Sensing.
	Adaptive Therapy icon – When moving, indicates a program that is sensing with Adaptive Therapy, and **BrainSense status** is set to **Adapting**. When not moving, indicates a program that is sensing with Adaptive Therapy where the program is inactive, Adaptive Therapy is **Paused**, or both.

Table 1. Definitions of buttons and icons (continued)

Button or icon	Definition
	Segment Mode button – Tap this button to turn Segment Mode On, which allows the configuration of individual electrode segments on a directional lead.
	Multiple rates button – Tap this button to access settings for the Multiple Rates feature.
	Anatomy button (if available) – Tap this button to import or view anatomy data.
	Info button – Tap this button to reveal more information.

HOME SCREEN

The **HOME** screen is the starting point for the various tasks and options within the clinician programmer application.

To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

Note: If you see the **MRI MODE ACTIVE** screen when you open the app, the paired neurostimulator is in MRI mode. See "MRI ELIGIBILITY OF THE DBS SYSTEM", page 48.

The **HOME** screen is primarily divided into two sections.

- **Left side has information –** The left side of the screen has patient and device information. If an impedance measurement was performed, it displays impedance status. If you have added clinician notes for the patient, those notes will be shown here. You can scroll up and down to view all the available information.

  Neurostimulator battery information is displayed under **DEVICE**. For more information on neurostimulator battery levels, see "NEUROSTIMULATOR BATTERY", page 53.
- **Right side has tasks –** The right side of the screen contains the list of tasks. You can tap a task in the list to start that task.

The **HOME** screen also has a menu button (in the top-left corner that gives you access to the following additional features.

- **Reports –** View, share, download, or delete various reports. For more information, see "REPORTS", page 63.
- **About –** View detailed information about the neurostimulator, communicator, patient control device, and clinician tablet. For more information, see "ABOUT SCREEN", page 65.
- **Preferences –** View and modify various settings and options that are indication-specific. These preferences endure beyond an individual programming session. For more information, see "PREFERENCES SCREEN", page 67.

After the **SETUP** workflow is complete, the following features are also available through the menu button.

- **Battery Longevity** – For the Percept PC neurostimulator, estimate the battery duration for the non-rechargeable neurostimulator based on stimulation settings. For more information, see "BATTERY LONGEVITY CALCULATOR SCREEN", page 66.
- **Recharge Interval** – For the Percept RC neurostimulator, estimate the recharge interval for the rechargeable neurostimulator battery based on the stimulation settings for the active group. For more information, see "RECHARGE INTERVAL CALCULATOR SCREEN", page 66.
- **BrainSense Surveys**– View and compare LFP signal strengths for available electrode configurations. For more information, see "BRAINSENSE SURVEYS SCREEN", page 67.
- **Usage –** View statistics about patient's use of the system. For more information, see "USAGE", page 70.

THE COMMUNICATOR

Using the communicator

Caution: Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI) such as radio frequency identification (RFID) equipment. EMI can interfere with telemetry during programming. If EMI disrupts programming, move the programming components away from the likely source of EMI.

The Model 8880T2 Communicator is intended for use by clinicians to use in conjunction with the clinician tablet and clinician programmer app for communication with Medtronic Neuromodulation medical devices.

The communicator is handheld and battery-powered. Communication between the communicator and a clinician tablet can occur wirelessly using BLUETOOTH® wireless technology or wired using the USB connector cable.

For information on the Model 8880T2 Communicator, including description, specifications, components, instructions for use, maintenance, and troubleshooting, refer to the Model 8880T2 Communicator Technical Manual.

Communicator icons in tablet status bar

Table 2 defines the icons that appear in the tablet status bar (uppermost row on the tablet screen) indicating the status of the communicator connection with the tablet.

Table 2. Communicator icons in the tablet status bar

Tablet status bar icon	Definition
	The communicator is in the process of connecting to the clinician tablet.
	The communicator is communicating with the clinician tablet via the USB connector cable.

Table 2. Communicator icons in the tablet status bar (continued)

Tablet status bar icon	Definition
	The communicator requires the USB connector cable to communicate with the clinician tablet.
	The communicator is communicating with the clinician tablet using BLUETOOTH wireless technology.

PAIRING THE COMMUNICATOR WITH THE CLINICIAN TABLET

Pairing the communicator with the clinician tablet

1. Connect the USB connector cable to the communicator and the clinician tablet.
2. Ensure that the communicator is turned on (slide the Power button down, then release).
3. A pop-up message may appear, which asks permission to open the Communication Manager app when the USB device is connected:
   a. Select to use the USB device by default. This selection prevents this pop-up message from appearing again.
   b. Select **OK**.
4. From the initial screen, tap **CONNECT**.

   Pairing begins and the communicator displays a green LED light between the tablet icon and the communicator icon.

   At this point, the communicator is paired with the clinician tablet and subsequent use of the communicator with the clinician tablet can use BLUETOOTH® wireless technology.

Communicator attempts to find the INS

1. The communicator is now ready to find the neurostimulator. Hold the communicator directly over the neurostimulator.

   Note: The target symbol (⊕) on the back of the communicator indicates the location of the internal antenna. The target should be facing and centered over the neurostimulator.
2. If multiple neurostimulators are found, use the serial number or nickname to confirm which neurostimulator the communicator should connect to.

Notes:

- **Percept neurostimulators only:** After making the initial connection, you can make future connections at a greater distance for 12 hours following the initial connection, or until the communicator connects to a different neurostimulator.
  - For best results over a greater distance, position the communicator so that one of its long sides is facing the neurostimulator.
- The resulting screen and workflow options to choose from will vary depending on whether the neurostimulator is new or already configured.
- If the **SETUP** task was not completed in a previous programming session, the workflow options for a new neurostimulator will display. Once the **SETUP** task is completed, the workflow options for a configured INS will display.

Refer to "PROGRAMMING THE INS", page 23 for information about configuring and programming the INS.

Refer to "Communicator and tablet troubleshooting", page 71 for troubleshooting problems related to the communicator.

USING THE EXTERNAL NEUROSTIMULATOR (ENS)

For instructions on programming the external neurostimulator with the Model A610 clinician programmer app, refer to the separate Model A610 Clinician Programming Guide that applies to the Model 37022 External Neurostimulator.

For instructions on using the external neurostimulator, refer to the external neurostimulator user manual.

TURNING STIMULATION ON OR OFF

You can turn stimulation on (or off (using the toggle at the top-right corner of the screen.

Note: While in MRI mode, you cannot turn stimulation on or off. See "To exit MRI mode", page 51.

Proximal telemetry confirmation for stimulation off (for patient)

Proximal telemetry confirmation (or “Close communication”) is an advanced setting available for the Percept neurostimulators that allows you to customize whether the patient must establish proximal telemetry before turning therapy off.

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen > Settings button

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program.
3. Tap the Settings button ( ) on the Programming screen.
4. Tap the **Device and Session** tab.
5. Tap the toggle button below **CLOSE COMMUNICATION REQUIRED FOR THERAPY OFF** to turn proximal confirmation on (or off ( ).

SETTING UP THE INS

This section is for setting up an implantable neurostimulator. For instructions on programming the external neurostimulator with the Model A610 programmer app, refer to the separate Model A610 Clinician Programming Guide that applies to the Model 37022 External Neurostimulator.

When connected to an implantable neurostimulator, the **SETUP** task is a process that enables you to set up a new patient and their implantable neurostimulation system.

The **SETUP** task can also be used to edit existing information that was entered during initial setup. The following subsections describe each screen of the setup task.

Entering general patient information

Quick navigation: HOME > SETUP > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **SETUP** and proceed to the setup task.
2. On the **Patient** screen, enter the patient and physician information.

   Notes:

   – Entering this patient data is required to import and view anatomy data.
   – Tap a text entry field and the keyboard will appear.
   – After patient health information is entered, that patient information is stored on the neurostimulator.
   – Tap the button (above the keyboard to close the keyboard.
3. Tap **UPDATE** or **NEXT** to continue.

Entering patient diagnostic information

Quick navigation: HOME > SETUP > OK > Tap Diagnosis

1. On the **Diagnosis** screen, select a diagnosis from the dropdown list.

   Note: Entering correct and complete patient baseline information will optimize the ability to track the patient's progress over time.
2. Tap **Yes** or **No** to indicate whether the patient is on medication during evaluation.
3. Optional) Add symptoms as needed. Up to five custom symptoms can be added.

   a. Tap **ADD SYMPTOM** (to add a symptom.
   b. Select a symptom from the dropdown list. You can also select **Custom** from the dropdown list and use the **DESCRIPTION** text entry field to enter a custom symptom name.
   c. If applicable, select a symptom detail from the dropdown list, or tap a region of the body on the right.
   d. Check a box under **SEVERITY** to apply a severity to the symptom.
   e. Tap **CONFIRM** to return to the **Diagnosis** screen.

   Note: Select the pencil icon (on an existing symptom to edit or delete that symptom.
4. Tap **UPDATE** or **NEXT** to continue.

Entering implanted component information

Quick navigation: HOME > SETUP > OK > Tap Components

1. On the **Components** screen, use the dropdown list to select the location of the neurostimulator.

Note: If no pocket adaptors are implanted, tap the checkbox below **ADAPTORS**.

2. Tap the plus icons (+ to select the connected components of the system.

   Notes:

   – If an adaptor is present, first select the adaptor and then select the lead.
   – To remove a component that was placed on a slot, tap the **X** near the component.
   – To swap the positions of the two leads, tap the button between the two leads (↓↑ and follow the on-screen prompts.
   – Take notice of the electrode numbers associated with each lead location, to aid in confirming system connection.

3. Tap the plus icon (+) next to **LEAD LOCATION** to select the location of the lead.
4. **Optional:** If a directional lead is implanted:

   a. On the Components screen, tap the plus icon (+ to configure lead orientation.
   b. Press, hold, and drag the control on the **ORIENTATION** screen to adjust the lead orientation.
   c. Tap **UPDATE**.

   Note: The **ANTEROPOSTERIOR** and **LATERAL** views on the left side of the **ORIENTATION** screen provide visual context for adjustment of lead orientation.

5. Tap **UPDATE** or **NEXT** to continue.

Entering abandoned components

Quick navigation: HOME > SETUP > OK > Tap Other

1. On the **Other** screen, tap the check box indicating whether the patient has any abandoned deep brain stimulation system components.
2. Tap **UPDATE** or **NEXT** to continue.

Activating the device

Quick navigation: HOME > SETUP > OK > Tap Activate

1. On the **Activate** screen, tap the **ACTIVATE DEVICE** ▷ button to activate the neurostimulator, which sets the current date as the implant date and begins the device service life.

   Note: After activation, the app will prompt a system connectivity test to confirm the system components selected on the **Components** screen. If this test encounters an issue, follow the on-screen prompts to resolve the issue.

2. Optional) Tap on the text field below **DEVICE NAME** to enter a name for the neurostimulator, to distinguish it from other neurostimulators.

   Note: Consider applicable privacy policies when choosing a name for the neurostimulator.

3. Tap **DONE** to complete the **SETUP** task.

CHARGE DENSITY

A survey of literature regarding electrical stimulation of neural tissue suggests that damage may occur above 30 microcoulombs/cm^2/phase. The Medtronic DBS System is capable of producing charge densities in excess of 30 microcoulombs/cm^2/phase. If the charge density threshold is reached, the Charge Density Warning appears.

Charge density depends on the delivered current. The delivered current remains constant regardless of therapy impedance.

Segments of the vertical slider bar on the Programming screen that are orange in color represent stimulation ranges that exceed 30 microcoulombs/cm^2/phase.

If an increase in stimulation causes the charge density to exceed 30 microcoulombs/cm^2/phase, the Charge Density Warning appears.

Note: If patient limits are programmed, the upper limit settings for amplitude and pulse width can also cause the Charge Density Warning to appear.

If the Charge Density Warning appears, and you wish to proceed with the programming change, tap the check box in the warning message to confirm, then tap the **OK** button to continue. The programmed stimulation value, as well as the Volume of Neuronal Activation (VNA) model, will display as orange in color until stimulation is reduced to a level below the charge density threshold.

STIMULATION SETTINGS OUT OF RANGE (OOR)

In certain situations, the neurostimulator battery may not be able to produce the levels of energy required for programmed settings.

Certain combinations of amplitude, pulse width, and rate settings are too high for the system to provide in its current state. When this happens, a Stimulation Settings Out Of Range (OOR) alert will appear, indicating that stimulation is not being provided at the level that is shown.

To resolve this, perform one of the following actions:

- Reduce stimulation parameters until the Out Of Range alert disappears.
- To achieve a high value for one parameter, reduce the other parameter values. For example, if high amplitude is desired, reduce the rate or the highest pulse width within the group.
- For rechargeable neurostimulators, check the battery level. If the battery level is low, consider recharging the neurostimulator.

For additional information on troubleshooting OOR errors, refer to "Stimulation Settings Out Of Range (OOR) troubleshooting", page 72.

PROGRAMMING THE INS

About programming

Notes:

- For information specific to programming with a directional lead, refer to "PROGRAMMING WITH A DIRECTIONAL LEAD", page 26.
- When changing therapy parameter settings, increase or decrease in small increments while evaluating the patient's response. See "ANNOTATIONS", page 31 for more information on recording patient response within the app.

Programming the neurostimulator consists of reviewing and modifying the information, settings, and optional features programmed in the neurostimulator. Information and settings may be from an earlier session or may be the default values.

- Stimulation parameters:
  - **Electrode polarities:** Programmed positive (+), negative (–), or off.
    - **Monopolar** (also called **unipolar** stimulation uses one or more lead electrodes as negative contacts, and the neurostimulator functions as the positive contact.
    - **Bipolar** stimulation uses one or more lead electrodes as negative contacts, and one or more lead electrodes as positive contacts.
  - **Amplitude:** Strength of each pulse in milliamps (mA).

    OptiStim™ control allows for the programming of multiple amplitude values in a single program. When programming multiple amplitude values in a single program, amplitude is defined as follows:
    - **Display amplitude** is a reference number that is displayed across the clinician programming app. It is also the amplitude value that the patient sees and adjusts on the patient control device.

      Limits are set for the entire stimulation shape; adjustments are performed on the amplitude tab of the programming screen when the ShapeLock Control button is selected.
    - **Delivered amplitude** is the amplitude that is delivered to individual active electrodes (levels or segments). Delivered amplitudes are fractions of the display amplitude. Delivered amplitudes cannot exceed the display amplitude.

      When an electrode's Delivered Amplitude is defined by the user, it is invisibly assigned a fraction. This fraction, when multiplied by the program's Display Amplitude, equals the Delivered Amplitude.
  - **Pulse width:** Duration of each pulse in microseconds (µs).
  - **Rate:** Frequency of pulses in hertz (Hz). By default, the rate is the same value across all programs in a group. Multiple rates can be programmed in a group. For more information on programming multiple rates, see "MULTIPLE RATES", page 30.

Programming settings

Programming settings are available by tapping the Settings button (⚙) on the Programming screen. These settings include, but are not limited to, the following.

- **SoftStart/Stop™ feature:** Slowly increases the amplitude when stimulation is turned on and slowly decreases the amplitude when stimulation is turned off, when cycling, or when changing groups.
- **Cycling:** Turns stimulation on and off at clinician-determined intervals.
- **Recharge Interval**: For the Percept RC neurostimulator, tap **Estimate** (▭) to enter the **RECHARGE INTERVAL CALCULATOR** screen. For more information, see "RECHARGE INTERVAL CALCULATOR SCREEN", page 66.
- **Patient Limits:** Sets the limits to which the patient can adjust a single parameter (amplitude, pulse width, or rate). Both an upper limit and a lower limit are set. For more information about limits, refer to "PATIENT LIMITS", page 33.

- **Amplitude Resolution and Range:** Allows adjustment of the resolution and range of the stimulation amplitude values for the respective hemisphere.

For information on multiple rates, refer to "MULTIPLE RATES", page 30.

For information on changing the default values of settings, refer to "PREFERENCES SCREEN", page 67.

Notes about programming:

- Using the lowest effective amplitude[2] and pulse width minimizes the charge density, the amount of stimulation applied to the patient over a given surface area. If programmed stimulation levels exceed the charge density threshold, an alert will appear. For more information on charge density, refer to "CHARGE DENSITY", page 22.
- For the Percept PC neurostimulator, using the lowest effective amplitude[2] and pulse width may increase battery longevity. For the Percept RC neurostimulator, using the lowest effective amplitude and pulse width may increase the recharge interval.
- Programs exist within groups. A group is a collection of up to four programs (two per hemisphere) that comprise stimulation settings for the patient at a given time. For more information about groups, refer to "MANAGING GROUPS", page 28.
- Increasing the amplitude takes effect gradually when ramping to the target value. Ramping can be adjusted or turned off for the current session through the Settings button (on the Programming screen.

To program

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program.

   Notes:

   – Only one group can be active at a time. To adjust an inactive program, tap the group that contains the program you want to adjust.
   – Consider using Electrode Identifier to inform initial programming. Refer to "To run Electrode Identifier", page 68.
3. Adjust programming settings using the following controls on the Programming screen (Figure 1).

   Note: Figure 1 is an example of the Programming screen for a 1x4 lead. For more information on programming options specific to a directional lead, refer to "To program with a directional lead", page 26.
4. When programming is complete, press the **Back** button (in the top-left corner to return to the **GROUPS** screen, or press the **Home** button (to return to the **HOME** screen.

[2] When programming multiple amplitude values in a single program, use the lowest effective delivered amplitude.

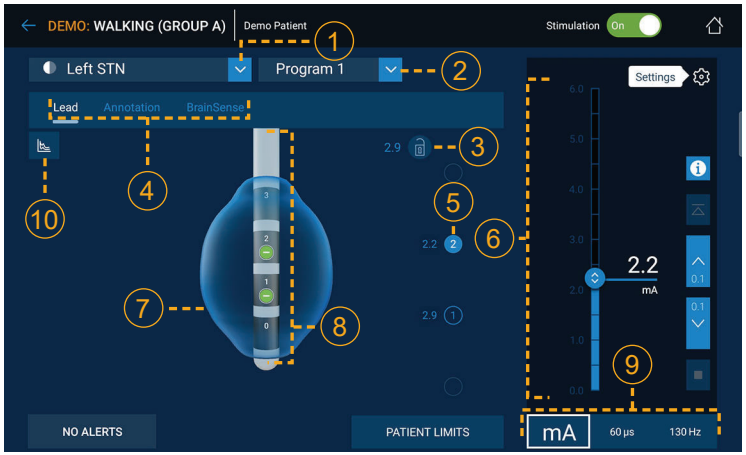

Figure 1. The Programming screen (1x4 lead shown).

①	**Lead location dropdown list –** Select a lead location to program.
②	**Program dropdown list –** Select a program.
③	**ShapeLock™ control –** When activated, polarities of all active electrodes are locked, and the amplitude of all active electrodes is increased or decreased in proportion to one another. **Note:** The number shown next to the ShapeLock control is the display amplitude.
④	**Navigation tabs –** Tap to view another screen.
⑤	**Electrode level button** – Tap an electrode level button to adjust amplitude for that electrode level only. OptiStim control allows you to assign a unique amplitude value to each electrode in the configuration. **Note:** The electrode level buttons are available when two or more negative ( ) electrodes are configured.
⑥	**Controls –** Adjust the selected stimulation parameter using either of the following controls:

(continued)

	■ Press and drag the slider ( ) on the vertical slider bar to adjust the parameter. ■ Tap the buttons at the right of the vertical slider bar to increase ( ) or decrease ( ) the selected parameter. **Amplitude only:** Ramping is enabled by default. You have the option to jump ( ) immediately to the target value, or stop ( ) at the current ramping value, which is shown at the right of the vertical slider bar while amplitude ramps. You can change the ramping interval through the Settings button ( ), in the **Device and Session** tab.
⑦	**VNA (Volume of Neuronal Activation) -** Provides a modeled, visual representation of the volume of neuronal tissue activated by the currently programmed settings. VNA is displayed during programming, modeling how changes in stimulation settings and electrode configurations affect the activated volume. The use of VNA does not replace observation of the patient for therapeutic effects or side effects.
⑧	**Electrode configuration –** Tap an electrode to change its polarity to negative ( ), positive ( ), or OFF ( ). Select at least one negative ( ) electrode. Tap **UPDATE** when you are done. The neurostimulator battery (case) will be set to positive polarity when electrode(s) on the lead are configured as negative only.
⑨	**Parameter tabs –** Select the parameter to be programmed: amplitude, pulse width, or rate.
⑩	**BrainSense Surveys button –** Select the BrainSense Surveys button to enter the BrainSense Surveys screen. After you run Electrode Identifier, this button appears as a dropdown menu. Select **View Electrode Identifier Results** from the dropdown menu to view Electrode Identifier results from the programming screen.

PROGRAMMING WITH A DIRECTIONAL LEAD

This section describes additional programming features and considerations specific to programming a directional (or segmented) lead.

For more information about general programming features and considerations, refer to "To program", page 24.

Note: In bipolar electrode configurations, all segments in the same level must be the same polarity.

About programming with a directional lead

Programming with a directional lead offers the potential to direct the field of stimulation more precisely.

For more information on directional leads, such as length, electrode spacing, and other specifications, refer to the appropriate lead manual.

Some indications include additional safety considerations when programming with directional leads. Refer to the appropriate information for prescribers addendum.

To orient a directional lead

If a directional lead has not already been oriented, follow these steps:

1. On the **HOME** screen, tap **SETUP** and proceed to the setup task.
2. Navigate to the **Components** screen.
3. Tap the orientation plus icon (+ to the right of the lead location.
4. Press, hold, and drag the controls on the **ORIENTATION** screen to adjust the lead orientation.

   Note: The **ANTEROPOSTERIOR** and **LATERAL** views on the left side of the **ORIENTATION** screen provide visual context for adjustment of lead orientation.
5. Tap **UPDATE** to apply the orientation.

To program with a directional lead

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (⌂ in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program.

   Notes:

   – Only one group can be active at a time. To adjust an inactive program, tap the group that contains the program you want to adjust.
   – Consider using Electrode Identifier to inform initial programming. Refer to "To run Electrode Identifier", page 68
3. Adjust general programming settings as needed. Refer to "To program", page 24 for more information.
4. Adjust programming settings specific to directional leads using the following controls on the Programming screen (Figure 2).

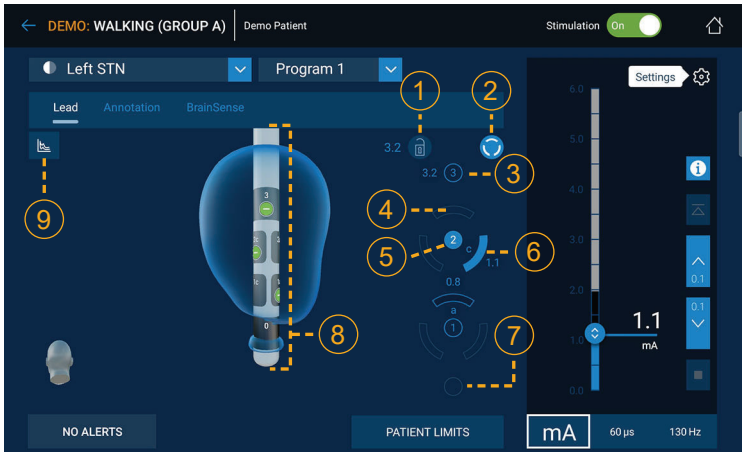

Figure 2. The Programming Screen (directional lead shown).

①	**ShapeLock control –** When activated, polarities of all active electrodes are locked, and the amplitude of all active electrodes is increased or decreased in proportion to one another. **Note:** The number shown next to the ShapeLock control is the display amplitude.
②	**Segment Mode button (shown in "On" state) –** When Segment Mode is On, you can program individual electrode segments on a directional lead.
③	**Active, non-selected electrode –** An electrode that is configured for stimulation (the delivered amplitude is shown next to it), but which is not selected for programming control.
④	**Inactive segment of a selected electrode level –** A segment of the selected electrode level that is not configured for stimulation. Active segments have a delivered amplitude value next to them and, when selected, are solid color (see callout #6, Active segment of a selected electrode level).
⑤	**Active, selected electrode level –** An electrode level with one or more segments actively configured for stimulation and selected for programming control. OptiStim control allows you to assign a unique amplitude value to each electrode in the configuration.

(continued)

⑥	**Active segment of a selected electrode level –** A segment of the selected electrode level that is configured for stimulation (the delivered amplitude is shown next to it). Inactive segments are outlined in color and do not have a delivered amplitude value next to them (see callout #4, Inactive segment of a selected electrode level).
⑦	**Inactive, non-selected electrode –** An electrode that is not configured for stimulation.
⑧	**Electrode configuration –** Tap an electrode (level or segment) to change its polarity to negative ( ), positive (, or OFF ( ). Select at least one negative ( ) electrode. Tap UPDATE when you are done. **Note:** Bipolar configurations are inaccessible when utilizing individual electrode segments. The neurostimulator battery (case) will be set to positive polarity when electrode(s) on the lead are configured as negative only.
⑨	**BrainSense Surveys button –** Select the BrainSense Surveys button to enter the BrainSense Surveys screen. After you run Electrode Identifier, this button appears as a dropdown menu. Select **View Electrode Identifier Results** from the dropdown menu to view Electrode Identifier results from the programming screen.

MANAGING GROUPS

A group is a collection of up to four programs (two per hemisphere) that comprise stimulation settings for the patient at a given time.

Setting up multiple groups for a patient allows quick and easy switching between stimulation settings. Using the **VIEW HISTORY** button, you can also view groups from previous sessions and copy them for use. See Figure 3, page 28.

SoftStart/Stop and cycling are always the same value across the programs in a group.

If a group has BrainSense™ configured, only one program per hemisphere is available. For more information, see "BRAINSENSE™ TECHNOLOGY", page 34.

To manage groups

Quick navigation: HOME > STIMULATION > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Adjust groups using the following controls on the **GROUPS** screen (Figure 3).
   - **To activate an inactive group:** Tap the inactive **GROUP** slot. The active group slot is outlined in white.

     Note: You must activate a group before adjusting any of the programs within that group.
   - **To name a group:** Tap **EDIT GROUP NAMES**, enter group names using the keyboard, then tap **UPDATE**.

     You can also edit a group's name through the Settings button (on the Programming screen.
   - **To copy a group or program:** Press and hold a group or program you wish to copy, then drag and drop the group or program into a highlighted slot. Individual programs with BrainSense cannot be copied.
   - **To delete a group or program:** Press, hold, and drag a group or program to the Trash slot (.

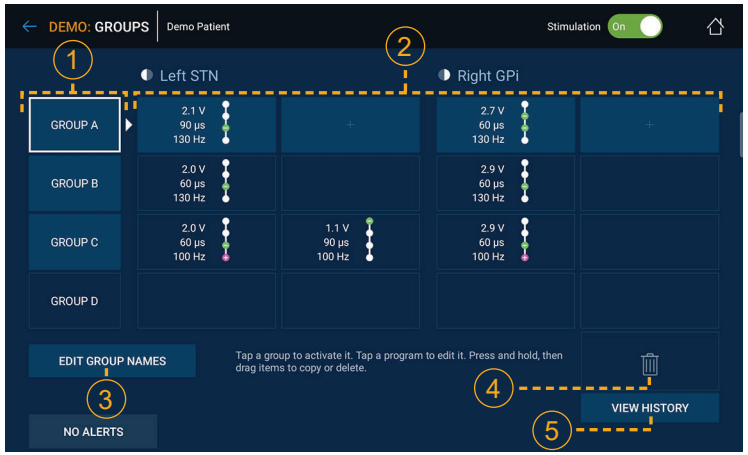

Figure 3. The GROUPS screen.

①	**Group slots –** Tap an inactive group slot to activate it. Only one group can be active at a time. Only the active group can be adjusted. Tap an unused group to create a new group.
②	**Program slots –** Tap an active program slot to adjust it on the Programming screen. To activate a program, activate the **GROUP** button on the same row.
③	**EDIT GROUP NAMES button –** Tap this button to edit group names.

(continued)

④	**Trash slot –** Press and hold, then drag and drop a group or program over this slot to delete it.
⑤	**VIEW HISTORY button –** Tap this button to view and, if desired, copy group settings from previous sessions. See "To view and import group history", page 29.

To view and import group history

Quick navigation: HOME > STIMULATION > OK > VIEW HISTORY

To view and import groups from previous sessions, start on the **GROUPS** screen.

1. From the **GROUPS** screen, tap the **VIEW HISTORY** button to view groups from previous sessions.

   Note: The history of previous groups is shown on the right side of the screen. Current groups are shown on the left side of the screen.

2. To import a group from the history, press and hold, then drag and drop a group from the right side to a group slot on the left side.

   Note: The app will ask for confirmation before overwriting a group with existing settings.

INTERLEAVING

About interleaving

Interleaving is a stimulation programming option that delivers pulses, which may have different amplitudes and pulse widths, to different electrodes, in an alternating manner.

Interleaving occurs whenever two programs are configured within the same hemisphere.

Interleaving may allow additional options when it is difficult to optimize stimulation.

Notes about interleaving:

- If you use interleaving in a hemisphere, you can set patient limits for one program, but not both.
- Interleaving must be removed from a group before that group can be configured for BrainSense.
- Amplitudes and pulse widths may be the same or they may differ between interleaved programs.
- SoftStart/Stop and cycling settings are always the same between interleaved programs.
- If multiple rates are not enabled, interleaving programs must have the same rate, which cannot exceed 125 hertz per program, or 250 hertz per hemisphere.
- If multiple rates are enabled, adjusting the rate of one program may affect available rates for all programs in the group. For more information on multiple rates, refer to "MULTIPLE RATES", page 30.

Interleaving on the Programming screen

Interleaving can be set up on the Programming screen by creating and configuring a second program within the same hemisphere.

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program.
3. Select **Program 2** from the **Program** dropdown list to set up the second program.

   For details on programming, see "To program", page 24.

Interleaving on the GROUPS screen

Interleaving can be set up on the **GROUPS** screen by copying any program onto an empty slot next to an existing program within a hemisphere.

Quick navigation: HOME > STIMULATION > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Press and hold, then drag and drop any existing program onto any empty slot within a hemisphere that contains only one program. For details on adjusting groups, see "To manage groups", page 28.

MULTIPLE RATES

About Multiple Rates

Through the Multiple Rates feature, the Percept neurostimulators have the capability to program multiple rates within a group.

Note: BrainSense and Multiple Rates cannot be used in a single group simultaneously.

To program with Multiple Rates

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program.
3. Tap the rate (Hz) parameter tab.
4. Tap the multiple rates ( ) button to access the **Multiple Rates** screen.
5. Tap the On/Off toggle to turn Multiple Rates on ( ) or off ( ).
6. Tap the **RATE 1** dropdown list and select the first rate.

   Note: The **RATE 1** value will determine which rates are available for **RATE 2**.
7. Tap the **RATE 2** dropdown list and select the second rate.
8. Tap a checkbox to select the rate for each configured program.
9. Tap **UPDATE** to apply the selected rates and return to the Programming screen.

ANNOTATIONS

The annotations feature of the app allows you to record the patient's response to specific therapy parameter settings.

Notes:

- Annotations are available only for configurations with a single configured electrode segment or level.
- Annotations are not available in groups that use multiple rates.

About annotations

Annotations are observed clinical effects of a single parameter combination, including electrode configuration, amplitude, pulse width, and rate. You can record an annotation for each combination of stimulation settings you evaluate.

Each stimulation parameter (amplitude, pulse width, rate) has its own annotation graph, but all three share one annotation history.

Each annotation can be assigned specific levels of observed therapeutic effect and, where applicable, undesired side effects.

These annotations can later be reviewed to determine which specific combinations of stimulation parameter settings result in the greatest therapeutic effect and the fewest or mildest side effects.

To create annotations

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen > Annotation tab

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Select the program for which annotations are to be recorded. Adjust stimulation as needed, then tap the **Annotation** tab.

1. Tap the **ANNOTATE** button (below the graph.
2. Record which symptoms the patient experiences with these stimulation settings and assign values to the level of those symptoms using the slider bar.[3]

   Notes about symptoms:

   – The default symptoms shown were selected based on the diagnosis entered during the **SETUP** task for the patient. See "SETTING UP THE INS", page 20 for details.
   – Applicable symptoms may vary from one patient to another. Symptoms also may vary depending on the indication being treated.
   – You can add customized symptoms by scrolling down and tapping the **ADD SYMPTOM** button (, or edit an existing customized symptom by tapping the pencil icon (.
3. Record which side effects the patient experiences with these stimulation settings, and assign numerical values to the level of those side effects using the slider bar.[3]

   Notes about side effects:

   – The default side effects shown were selected based on the diagnosis entered during the **SETUP** task for the patient. See "SETTING UP THE INS", page 20 for details.
   – Applicable side effects may vary from one patient to another. Side effects also may vary—or may not be a factor—depending on the indication being treated.
   – You can add customized side effects by scrolling down and tapping the **ADD SIDE EFFECT** button (, or edit an existing customized side effect by tapping the pencil icon .

[3] Depending on the indication, SYMPTOMS and SIDE EFFECTS may be recorded as OBSERVATIONS. This also changes the labels on the scales.

To edit annotations

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen > Annotation tab

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Select the program for which annotations are to be recorded. Adjust stimulation as needed, then tap the **Annotation** tab.

1. Tap the **ANNOTATE** button (below the graph, or tap the horizontal bar on the graph for the annotation you wish to edit.
2. As needed, revise which symptoms the patient experiences with these stimulation settings, and revise the numerical values for the severity of those symptoms.
3. Tap **UPDATE** to confirm the edits.

   Note: While editing an annotation, you can delete the entire annotation by tapping the **DELETE** button.

To view annotations history

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen > Annotation tab

Begin on the **Annotation** screen. To navigate to the **Annotation** screen, tap the **Home** button (in the top-right corner. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Select a program, then tap the **Annotation** tab.

1. Tap the **HISTORY** button (.

   Note: The **HISTORY** screen has two views, each represented by a tab at the top. The default view is **Table**. Tap the **Graphs** tab to change to a graph view. For details on the **Graphs** tab, see Steps 3-4 below.
2. Review the **HISTORY** screen using the **Table** tab, which visually presents a history of annotations recorded over time.
   - Each row represents a separate annotation that was recorded using the settings shown in the far left column.
   - The far-left column shows the settings used and the date when the annotation was recorded.
   - Other columns represent symptoms and side effects.
   - Swipe up and down to view additional annotations, if applicable.
   - Swipe left and right to view additional symptom and side effect ratings, if applicable.
3. To view the graph view, tap the **Graphs** tab above the table.
4. Review the **HISTORY** screen using the **Graphs** tab, which shows different graphical views of annotations based on the stimulation parameter selected.
   - Each graph shows one or more annotations recorded for a single parameter (eg, amplitude).
   - The date of the annotations is labeled above the graphs.
   - Swipe left and right to view additional sessions and annotations, if applicable.

PATIENT LIMITS

About patient limits

The patient limits feature, when enabled, allows you to set limits for the patient to control one parameter of his or her stimulation. The range of stimulation accessible to the patient can be defined by setting an upper limit and a lower limit.

The default setting for patient limits is off.

Notes:

- If Limit flags are not shown when using multiple cathodes in a program, activate the ShapeLock control (to access the Limit flags.
- If you use interleaving in a hemisphere, you can set patient limits for one program, but not both.

To set patient limits

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Tap any active program to proceed to the Programming screen.

1. On the Programming screen, tap the **PATIENT LIMITS** button.

   Note: You can also tap the Settings button (in the top-right corner of the Programming screen, then tap the pencil icon under **ADJUSTABLE PARAMETER** in the **Patient Limits** section of the screen.

2. In order to set patient limits, tap **Advanced Adjust**.

More information about patient limit modes:

There are three patient limits modes: **Simple**, **Advanced View**, and **Advanced Adjust**.

- **Simple** mode allows the patient to turn stimulation on and off and check battery status.
  - **Simple** mode is available only when one group is configured.
- **Advanced View** mode, with two or more groups, allows the patient to view their stimulation level, and to switch between groups. **Advanced View** mode is automatically selected if you configure a second group while in **Simple** mode.
  - If the patient uses the Model A620 Patient Programming Application with one group available, **Advanced View** mode is the same as **Simple** mode.
- **Advanced Adjust** mode is the only mode that allows the patient to adjust stimulation within patient limits.
  - Patient limits can only be set while in **Advanced Adjust** mode.
  - Any existing patient limits for a group will be removed if **Simple** or **Advanced View** mode is selected for that group.

3. Tap the parameter you want the patient to have the ability to adjust: amplitude, pulse width, or rate.
4. Tap **UPDATE** to return to the Programming screen.
5. Use the controls to set patient limits (Figure 4).

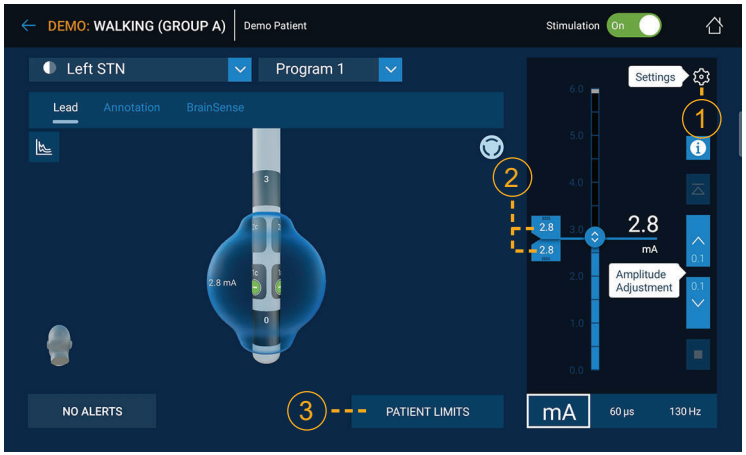

Figure 4. Patient limits on the Programming screen.

①	**Settings button –** Allows you to adjust the program to which patient limits are applied: **Program 1** or **Program 2**. By default the app applies patient limits to Program 1.
②	**Limit flags –** Allows adjustment of the upper and lower limits of stimulation accessible to the patient. If two programs are active, use the **Program** dropdown list to switch programs. **Note:** If using multiple amplitudes in a program, activate the ShapeLock control ( ) to access the Limit flags.
③	**PATIENT LIMITS button –** Allows access to Patient Limits modes and settings.

Note: Orange segments on the stimulation slider bar represent stimulation levels above the charge density threshold. Patient limits are considered when calculating charge density; therefore, if the upper limit exceeds the charge density threshold, a charge density alert will appear. See "CHARGE DENSITY", page 22 for more information.

BRAINSENSE™ TECHNOLOGY

BrainSense is a set of features available with the Percept neurostimulators. BrainSense has two modes: Sensing and Adaptive Therapy.

BrainSense has three possible statuses: **Off**, **Sensing Only**, and **Adaptive** (see Table 3).

Table 3. BrainSense statuses

BrainSense State	Description
Off	■ Sensing is not recording Local Field Potential (LFP) data. ■ Adaptive Therapy is disabled or not configured. ■ When patient limits are configured, the patient can manually adjust amplitude.[a]
Sensing Only	■ Sensing is recording Local Field Potential (LFP) data. ■ Adaptive Therapy is disabled or not configured. ■ When patient limits are configured, the patient can manually adjust amplitude.[a]
Adaptive	■ Sensing is recording Local Field Potential (LFP) data. ■ Adaptive Therapy can either be set to **Adapting** ( ) or **Paused** ( ). For information on pausing Adaptive Therapy, see "To pause Adaptive Therapy", page 43. ■ When Adaptive Therapy is configured for one or both hemispheres, the patient can pause or resume Adaptive Therapy. The patient cannot manually adjust amplitude on either hemisphere.

a Pulse width and rate cannot be adjusted once BrainSense has been set up for either hemisphere. To reenable pulse width or rate patient limits, BrainSense must be removed from the group. Refer to "To remove BrainSense from a group", page 44.

More information about BrainSense:

- BrainSense cannot be configured in a hemisphere that includes a pocket adaptor.
- BrainSense and Multiple Rates can not be used in a single group simultaneously.
- For a group configured with BrainSense, maximum pulse width and maximum rate are lower than a group without BrainSense configured. Minimum rate is higher than a group without BrainSense configured.

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More information about BrainSense:

- Interleaving is not available in groups with BrainSense configured.
- BrainSense is automatically disabled when a neurostimulator enters MRI mode. BrainSense is automatically enabled when the neurostimulator exits MRI mode.
- BrainSense is automatically disabled during a recharging session. BrainSense is automatically enabled when the recharging session ends.
- BrainSense LFP data is not recorded during an impedance test. It is automatically resumed when the test is complete.

About BrainSense technology

By sensing with two electrodes on the lead, the Percept neurostimulators have the capability to measure and record electrical signals from the brain.

The signal captured by the neurostimulator is the local field potential LFP) which represents the oscillatory activity of the neuronal population surrounding the recording electrodes.

LFP signals may respond to stimulation amplitude changes and other factors.

About Adaptive Therapy

Adaptive Therapy is a therapy option for the Parkinson's disease indication in patients who have a single Percept neurostimulator. Adaptive Therapy measures the LFP signal and, as the LFP signal changes relative to LFP thresholds, it automatically adjusts stimulation amplitude within clinician-defined stimulation limits. It allows a clinician to configure stimulation amplitude to automatically adjust based on the changes to sensed brain signals.

Note: In patients with Parkinson's disease, Alpha-Beta LFP power generally decreases in the following situations:

- in response to increased DBS stimulation amplitude
- in response to effective Parkinson's disease medication
- during some non-REM sleep stages

Most patients with Parkinson's disease have an adequate LFP for use with Adaptive Therapy, however, some patients may not. Evaluate the patient's response to Adaptive Therapy before finalizing Adaptive Therapy settings.

Important information about Adaptive Therapy:

- The Paused Amplitude is the stimulation amplitude the patient will receive when Adaptive Therapy is Paused. The patient will receive this therapy until Adaptive Therapy is Resumed. **Setting the Paused Amplitude is necessary to ensure that patients can pause Adaptive Therapy due to stimulation-related side effects or non-optimized Adaptive Therapy.** For instructions on setting the Paused Amplitude value for a group, refer to "To set up or adjust Adaptive Therapy", page 41.
- Patients cannot directly increase or decrease stimulation while in a group in which **BrainSense Status** is **Adaptive**, but the patient has other ways to control stimulation using the patient control device:
  - The patient can turn stimulation on and off.
  - The patient can pause or resume Adaptive Therapy. (When Adaptive Therapy is paused, stimulation amplitude defaults to the Paused Amplitude value.)
  - The patient can switch groups, if other groups are available.
- Patient Limits (as described on page 33), which allow patients to adjust a stimulation parameter from their patient programming application, are not available with Adaptive Therapy. Instead, Adaptive Therapy uses its own set of limits, which are established in the **BrainSense Setup** workflow and cannot be adjusted by the patient.
- For a group configured with Adaptive Therapy, maximum pulse width and maximum rate are lower than a group without Adaptive Therapy configured. Minimum rate is higher than a group without Adaptive Therapy configured.
- Interleaving and cycling are not available in groups with Adaptive Therapy.
- Adaptive Therapy relies on LFP signals that respond to stimulation amplitude changes. If a patient's LFP signal does not respond in this way, Adaptive Therapy may not be optimal for the patient.
- A few programming adjustment visits may be needed in the first few months after turning on Adaptive Therapy. Patients programmed with Adaptive Therapy may require more programming adjustment visits if they experience stimulation-related side effects or need to further personalize programming settings.
- Electromagnetic Interference (EMI) may be misinterpreted as LFP signal during sensing and cause an increase or decrease in stimulation amplitude. However, the stimulation amplitude is restricted to within the clinician-defined Adaptive Amplitude Limits. If patients experience fluctuations in Adaptive Therapy, patients can move away from the source of the EMI, pause Adaptive Therapy, switch groups, or turn the stimulation off. Adaptive Therapy has not been studied in patients with other active implanted devices (for example, pacemaker, defibrillator, neurostimulator, cochlear implant).
- Adaptive Therapy has only been studied in patients with a single Percept neurostimulator. Adaptive Therapy should **NOT** be configured in patients who have two neurostimulators. Similar to EMI, stimulation from another

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Important information about Adaptive Therapy:

neurostimulator may be misinterpreted as LFP signal during sensing and cause an increase or decrease in stimulation amplitude. However, the stimulation amplitude is restricted to within the clinician-defined Adaptive Amplitude Limits. If patients experience fluctuations in Adaptive Therapy, patients can pause Adaptive Therapy, switch groups, or turn the stimulation off.

- Adaptive Therapy is automatically paused during a recharging session. Adaptive Therapy is automatically resumed when the recharging session ends. When setting up Adaptive Therapy, review the Paused Amplitude to ensure patient comfort during recharging sessions.
- Adaptive Therapy is temporarily disabled during an impedance test. It is automatically re-enabled when the test is complete.
- Adaptive Therapy is **NOT** an eligible stimulation option for use during MRI mode. To enter MRI mode, the patient or clinician must turn stimulation off for a group configured for Adaptive Therapy or switch to a group with a bipolar configuration.
- Adaptive Therapy can influence battery longevity or recharge intervals. Monitor these values to determine if Adaptive Therapy should be continued.

To set up or adjust BrainSense

Quick navigation: HOME > STIMULATION > OK > Tap active program in a non-interleaved group > BrainSense tab

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Tap any non-interleaving, active program and proceed to the Programming screen.

1. On the Programming screen, tap the **BrainSense** tab.
2. If applicable, pause Adaptive Therapy.
3. Tap **SETUP** to begin the **BrainSense Setup** workflow.
4. Tap **RUN SIGNAL TEST** or the icon next to it (.

Notes:

- Patients should minimize movements to reduce artifacts in the initial signal test.
- If you have not yet run an impedance test in this programming session, you will be prompted to run an impedance test. The impedance test is required to continue with the **BrainSense Setup** workflow.
- If a sense channel has already been configured and you wish to adjust the configuration of BrainSense, tap **REFRESH SIGNAL TEST**.

5. Press **START** to run the signal test. When the signal test is complete, the **Signal Test** results screen appears (Figure 5).

Note: If no signal is detected, tap **REFRESH SIGNAL TEST** to repeat the signal test. For more information on BrainSense troubleshooting, see "BrainSense troubleshooting", page 72.

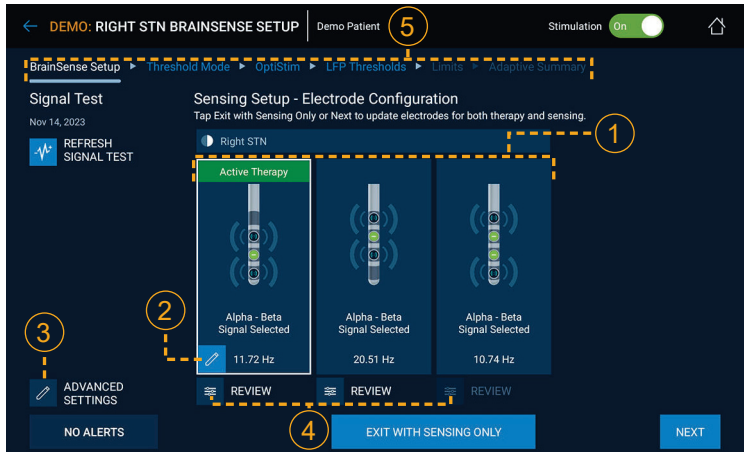

Figure 5. The Signal Test results screen (workflow for directional lead shown).

①	**Electrode configurations –** Allows you to select an electrode configuration for BrainSense and stimulation.
②	**Frequency band button –** Allows you to adjust the frequency band of the selected electrode configuration.
③	**ADVANCED SETTINGS button –** Allows you to access advanced settings for Sensing. (More settings become available as you progress through the **BrainSense Setup** workflow.)
④	**REVIEW buttons –** Allows you to review annotations history for a configuration.
⑤	**BrainSense Setup workflow navigator** – The workflow navigator is displayed at the top of every screen when you are in the BrainSense Setup workflow and represents the tasks that are to be completed on each screen as they appear. 1. A title that is bold and underlined in the workflow navigator indicates your position in the workflow. 2. The **NEXT** and **PREVIOUS** buttons move forward or backward through the workflow.

6. Select one of the available electrode configurations for stimulation and BrainSense.

   Notes:

   – Under an available electrode configuration, tap the pencil icon (to enter the **FREQUENCY BAND** screen, where you can view the LFP signal captured during the signal test and use the horizontal slider (to select the signal frequency range of interest. The blue-tinted bar around the selected frequency shows the range of frequencies that will be sensed.

   – You can tap **ADVANCED SETTINGS** or the pencil icon (next to it to enter the **ADVANCED SETTINGS** screen, where you can adjust advanced Sensing parameters (Table 4).

More information about selecting an electrode configuration for BrainSense:

– Consider the patient's underlying neurological condition when determining the LFP frequency of interest.

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More information about selecting an electrode configuration for BrainSense:

– If one of the configurations shown is currently being used to deliver therapy, a green **Active Therapy** message will be displayed above it.
– Unavailable configurations are grayed out.
– Adaptive therapy is only available for electrode configurations with a signal of interest within the Alpha-Beta frequency range (8-30 Hz). To enable Adaptive Therapy, adjust the sense frequency to be within the Alpha-Beta range.
– To successfully capture LFP thresholds and set up Adaptive Therapy, it is recommended that you select an electrode configuration with an Alpha-Beta band LFP amplitude greater than 1.2 µVp.
– Changing electrode configuration will reset amplitude to zero. This will also clear captured thresholds and BrainSense configuration.
– **For Dual Lead Implants Only:** When the hemisphere contralateral to the selected hemisphere has been set up for BrainSense, it appears on the Signal Test screen as an option for Sensing. Select the contralateral hemisphere to use the Sensing data from that hemisphere's lead to drive Adaptive Therapy for the selected hemisphere. This setup is an option for situations when configurations on the currently selected lead are not acceptable for Sensing setup. For example, when electrode 0, electrode 3, or bipolar stimulation is desired.

Note: The settings available for adjustment vary based on your position in the workflow.

7. Tap **Exit with Sensing Only** to configure Sensing for this hemisphere.

   Tap **NEXT** to capture LFP thresholds or set up Adaptive Therapy. Refer to "Selecting a Threshold Mode", page 38 and "To set up or adjust Adaptive Therapy", page 41.

Table 4. Advanced settings for Sensing

Setting	Function
High Pass Filter	LFP frequency band data below the high pass filter will be reduced.
Sensing Blanking Duration	Sensing Blanking Duration reduces noise introduced by stimulation. A longer duration reduces the noise to a greater extent than a shorter duration.
Averaging Duration	Averaging Duration reduces noise by averaging the signal over a duration and assigning it a single value. A longer duration may reduce noise to a greater extent than a shorter duration. A shorter duration may result in a faster LFP response when streaming BrainSense data.

Selecting a Threshold Mode

Quick navigation: HOME > STIMULATION > OK > Tap actively sensing program > BrainSense tab > SETUP > NEXT

To select a Threshold Mode, you must first configure Sensing. Refer to "To set up or adjust BrainSense", page 36.

1. Navigate to the **Threshold Mode** tab of the **BrainSense Setup** workflow.
2. Select **Dual Threshold**, **Single Threshold**, or **Single Threshold Inverse** (Sensing Only). Refer to "General characteristics of Threshold Modes", page 38.

   Note: For more information about Threshold Modes, tap **MORE INFO** at the top right corner of the screen.
3. Tap **NEXT** to continue.

   If using a directional lead, continue to "Directing stimulation when BrainSense is configured (directional lead only)", page 39. If using a 1x4 lead, continue to "Capturing or recapturing LFP thresholds", page 39.

General characteristics of Threshold Modes

This section describes the general characteristics of each of the Threshold Modes.

Note: Adaptive Therapy can be configured in either Dual Threshold Mode or Single Threshold Mode. Configuring Adaptive Therapy in Dual Threshold Mode has been shown to increase "On" time without troublesome dyskinesia, and to decrease "Off" time. However, Single Threshold Mode may be preferred for some patients.

- **Dual Threshold –** Dual Threshold Mode uses an upper and lower LFP threshold to track LFP (e.g, Alpha-Beta) changes. Higher LFP is associated with lower stimulation and lower LFP is associated with higher stimulation.
  - **Adaptive –** While adapting, this provides a slower stimulation amplitude reaction to LFP (e.g, Alpha-Beta) changes (e.g, due to medication cycles), by default on the order of minutes, to keep the LFP between two thresholds. When the LFP passes above the upper threshold, the stimulation amplitude slowly ramps up. When the LFP passes below the lower threshold, the stimulation amplitude slowly ramps down
- **Single Threshold –** Single Threshold uses a single LFP threshold to track LFP (e.g, Alpha-Beta) changes. Higher LFP is associated with lower stimulation and lower LFP is associated with higher stimulation.
  - **Adaptive –** While adapting, this provides a faster stimulation amplitude reaction to LFP (e.g, Alpha-Beta) changes, by default on the order of milliseconds, to keep the LFP below a single LFP threshold. When the LFP passes above the LFP threshold, the stimulation amplitude rapidly ramps up. When the LFP passes below the LFP threshold, the stimulation amplitude rapidly ramps down.
- **Single Threshold Inverse –** Single Threshold Inverse uses a single LFP threshold to track LFP (e.g, Gamma) changes. Higher LFP is associated with higher stimulation amplitude and lower LFP is associated with lower stimulation amplitude.

Note: Single Threshold Inverse is only available in a Sensing Only configuration.

More information about Threshold Modes:

- When a Threshold Mode is selected and configured for Sensing Only, a change in LFP power will not cause an automatic change in stimulation amplitude.
- The rate at which stimulation increases and decreases in response to LFP signal is determined by the Transition Up and Transition Down durations.
- The same Threshold Mode is used for all aDBS programs in a group.
- If both hemispheres have an Adaptive Therapy program configured in Single Threshold Mode, Sensing LFP data from either hemisphere will drive Adaptive Therapy.
- In Dual Threshold Mode, stimulation amplitude is driven from Sensing data from the same hemisphere, unless a contralateral Sensing configuration is setup.

Directing stimulation when BrainSense is configured (directional lead only)

Quick navigation: HOME > STIMULATION > OK > Tap actively sensing program > BrainSense tab > SETUP > Tap NEXT until OPTISTIM screen appears

1. Navigate to the **OptiStim** tab of the **BrainSense Setup** workflow.
2. Adjust general programming settings as needed. Refer to "To program", page 24 for more information.
3. Adjust programming settings specific to directional leads as needed. Refer to "To program with a directional lead", page 26.

   Notes:

   – Vertically aligned segments must have the same amplitude and electrode polarity when BrainSense is configured.
   – Changing electrode configuration after this point may clear patient limits and the amplitudes used to capture LFP thresholds. LFP thresholds will be retained.
4. Tap **NEXT** to continue to the **LFP Thresholds** screen.

Capturing or recapturing LFP thresholds

Quick navigation: HOME > STIMULATION > OK > Tap actively sensing program > BrainSense tab > SETUP > Tap NEXT until LFP THRESHOLDS screen appears

Information about LFP Thresholds:

- The patient should be seated and minimize movement during LFP threshold capture.
- Capturing an LFP threshold records the power of the LFP signal at a selected stimulation amplitude. Stimulation adjustment is the means to elicit changes in the LFP signal. LFP thresholds may be adjusted after initial capture, as desired.
- While Sensing, LFP Thresholds act as reference points that may be utilized to understand variations in LFP power over time (see Figure 6). For example, the LFP Chart tab on the **EVENTS** screen displays the percentage of time a patient's LFP was measured as above the upper threshold, below the lower threshold, or between the two thresholds. Refer to "LFP Chart", page 56.
- Adaptive Therapy automatically increments stimulation amplitude when the measured LFP signal crosses an LFP threshold as described in "General characteristics of Threshold Modes", page 38.

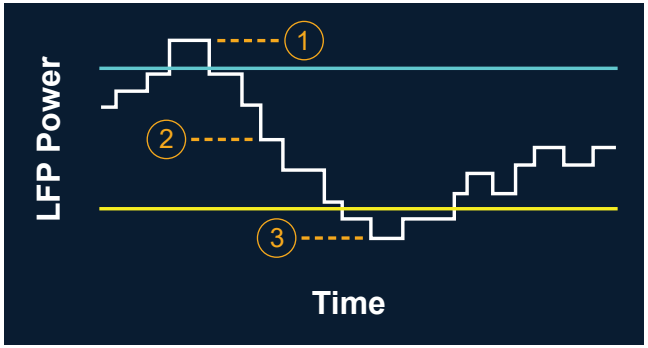

Figure 6. LFP signal and LFP thresholds (Dual Threshold shown).

① LFP signal shown above Upper LFP Threshold.
② LFP signal shown between the Upper and Lower LFP Thresholds.
③ LFP signal shown below Lower LFP Threshold.

To capture LFP thresholds, you must first:

- Set up Sensing, refer to "To set up or adjust BrainSense", page 36.
- Select a Threshold Mode, refer to "Selecting a Threshold Mode", page 38.

1. Navigate to the **LFP Thresholds** tab of the **BrainSense Setup** workflow.
2. Capture LFP thresholds.

   Note: The number of LFP measurements you capture, and the steps needed to capture them, depend on the Threshold Mode.
3. Follow the steps in Table 5 for the Threshold Mode you selected.

Table 5. Steps to capture LFP for each Threshold Mode

Dual Threshold	1. Set the stimulation amplitude to the Lower Limit of therapeutic benefit for the patient. 2. Tap **Capture LFP** ( ) to capture the Upper LFP Threshold at that amplitude. 3. Increase the stimulation amplitude to the Upper Limit of therapeutic benefit for the patient. 4. Tap **Capture LFP** ( ) to capture the Lower LFP Threshold at that amplitude.
Single Threshold	1. Increase the stimulation amplitude to the Upper Limit of therapeutic benefit for the patient. 2. Tap **Capture LFP** ( ) to capture LFP data at that amplitude. **Note:** The app will automatically capture a second LFP signal with amplitude set to 0 mA, and generate a single threshold value based on the two LFP signals.
Single Threshold Inverse	1. Set the stimulation amplitude to the Lower Limit of therapeutic benefit for the patient. 2. Tap **Capture LFP** ( ) to capture LFP data at that amplitude. 3. Increase the stimulation amplitude the Upper Limit of therapeutic benefit for the patient. 4. Tap **Capture LFP** ( ) to capture LFP data at that amplitude. **Note:** The app will automatically generate a single threshold value based on the two LFP signals.

Note: For information on troubleshooting steps related to capturing LFP thresholds, see "BrainSense troubleshooting", page 72.

4. After capturing thresholds, return the stimulation amplitude to a comfortable level.
5. To adjust an LFP threshold, tap the adjust thresholds toggle and use the controls identified in Figure 7.

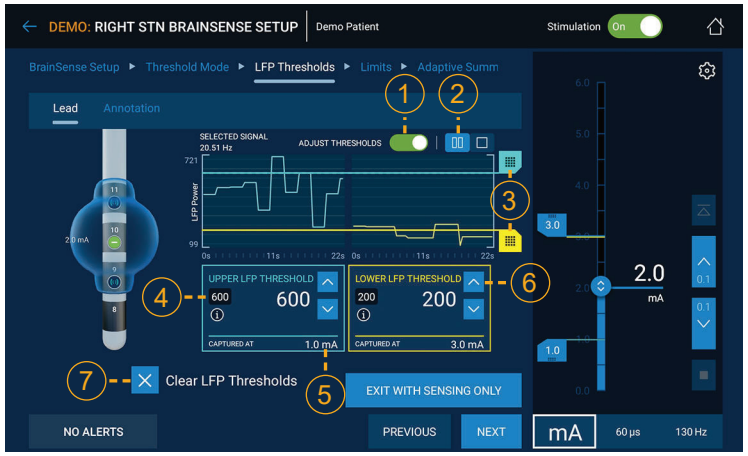

Figure 7. LFP Thresholds Capture screen (Dual Threshold mode shown).

①	**Adjust thresholds toggle -** Tap the Adjust Thresholds On/Off toggle to display the captured threshold power data and enable manual changes to the captured LFP threshold(s) ( ). Turn the Adjust Thresholds On/Off toggle to off ( ) to hide captured threshold power data and disable manual changes to captured LFP threshold(s).
②	**Combine graphs toggle -** To combine capture data onto one graph, set the toggle to combine . To divide capture data into two graphs set the toggle to separate .
③	**LFP threshold adjustment flag -** To manually adjust the captured LFP threshold(s), slide the adjustment flag ( ) on the graph to increase or decrease the corresponding captured LFP threshold.
④	**Captured LFP power -** This number represents the LFP power of the selected frequency band. It is calculated as the sum of the squared LFP magnitude at each frequency within the selected band, similar to the Area Under the Curve. The captured LFP power shows the value at the time of threshold capture, before any adjustments to the LFP Thresholds are made.
⑤	**Amplitude used to capture LFP threshold -** Reference this number to see the stimulation amplitude delivered when the LFP threshold was captured. **Note:** The amplitude used to capture LFP threshold is also shown as a line on the vertical slider bar.
⑥	**LFP threshold adjustment arrows -** Increase or decrease an LFP threshold by one unit by tapping the up or down arrow.
⑦	**Clear LFP Thresholds button -** To clear captured LFP threshold data and recapture thresholds, press Clear LFP Thresholds.

If you want to save and exit at this point, tap the **EXIT WITH SENSING ONLY** button. This enables Sensing, but stimulation will not adapt automatically in response to the sensed LFP signal.

To set up Adaptive Therapy, continue to the next section.

To set up or adjust Adaptive Therapy

Quick navigation: HOME > STIMULATION > OK > Tap actively sensing program > BrainSense tab > SETUP > Tap NEXT until the LIMITS screen appears

To set up Adaptive Therapy, you must first:

- Set up Sensing, refer to "To set up or adjust BrainSense", page 36.
- Select a Threshold Mode, refer to "Selecting a Threshold Mode", page 38.
- Capture LFP thresholds, refer to "Capturing or recapturing LFP thresholds", page 39.

1. Navigate to the **Limits** tab of the **BrainSense Setup** workflow.
2. Review Adaptive Amplitude Limits. To adjust the maximum and minimum amplitude for Adaptive Therapy, slide the limit flags on the vertical slider bar.

More information about Adaptive Amplitude Limits:

- The Adaptive Amplitude Limits represent the maximum and minimum stimulation amplitudes allowed during adaptive stimulation. The system will automatically adjust stimulation between these limits in response to LFP power as defined by the selected Threshold Mode.
- When stimulation amplitude reaches the Adaptive Amplitude Limit, stimulation stays at this limit until the LFP signal crosses a threshold as described in "General characteristics of Threshold Modes", page 38.
- Adaptive Amplitude Limits will default to the stimulation amplitude values used when capturing LFP Thresholds; however, they are adjustable by using the limit flags on the vertical slider bar.
- When BrainSense status is changed from **Adaptive** to **Sensing Only** for all adaptive programs in a group, the values selected for the Adaptive Amplitude Limits will become patient limits.

3. Review the Paused Amplitude. To change the Paused Amplitude, press and drag the slider ( ) on the vertical slider bar.
4. Tap **NEXT** to proceed to the **Adaptive Summary** tab.
5. Review settings and make adjustments if needed.

More information about the Adaptive Summary tab:

- To run a Transition Test, tap the pencil icon ( ) under **TRANSITION DURATIONS**. See "About Transition Durations", page 42 for instructions on performing a transition test.

(continued)

More information about the Adaptive Summary tab:
– You can tap **ADVANCED SETTINGS** or the pencil icon (next to it to enter the **ADVANCED SETTINGS** screen, where you can adjust the detailed behaviors of Sensing and Adaptive Therapy. See Table 6 for details about these advanced settings.

6. If applicable, tap **Start Adaptive Therapy** to begin Adaptive Therapy. Or, tap **Save & Exit** to save any adjustments made to Adaptive Therapy in the current workflow session. You will be returned to the **BrainSense** tab of the Programming screen.

Table 6. Advanced settings for Adaptive Therapy

Setting	Function
Onset Duration	The amount of time that the LFP signal must remain above the upper threshold, or below the lower threshold, before the system classifies the LFP state as above or below the threshold and initiates a consequent change in stimulation amplitude. These parameters may need to be adjusted if Adaptive Therapy transiently delivers stimulation that is too low or too high to achieve the desired therapeutic result.
Detection Blanking Duration	Once the system classifies an LFP signal as above or below a threshold, it will not attempt to re-classify the LFP signal until after the Detection Blanking Duration. This parameter may need to be increased if while streaming in Single Threshold Mode, Adaptive Therapy repeatedly ramps to the upper stimulation limit immediately after stimulation adjusts to the lower limit.
Adaptive Startup Delay	The delay after switching to, or activating, Adaptive Therapy before automatic adjustments to stimulation begin. This parameter may need to be increased if Adaptive Therapy transiently delivers stimulation at the upper limit immediately after Resuming or activating Adaptive Therapy.

To modify settings for an existing adaptive program, re-enter the **BrainSense Setup** workflow with BrainSense status set to **Adaptive** and Adaptive Therapy Paused.

The Adaptive Amplitude Limits and Paused Amplitude are modifiable on the **Lead** and **BrainSense** tabs of the Programming screen.

Additionally, LFP thresholds may be adjusted while streaming BrainSense data. Refer to "About streaming of BrainSense data", page 44.

About Transition Durations

When Adaptive Therapy is set to **Adapting**, Transition Durations determine the speed with which stimulation amplitude automatically increases or decreases in response to changes in the LFP signal.

Consider testing the Transition Durations to ensure that the patient can tolerate the speed of amplitude changes he or she will encounter while using Adaptive Therapy.

To set Transition Durations

To set **TRANSITION DURATIONS**, first navigate to the **Summary** tab of the **BrainSense Setup** workflow. See "To set up or adjust BrainSense", page 36.

1. On the **Summary** tab of the **BrainSense Setup** workflow, tap the pencil icon (next to **TRANSITION DURATIONS**.
2. Use the slider (on the pink horizontal bar to set the **Transition Up Duration**.
3. Use the slider (on the green horizontal bar to set the **Transition Down Duration**.
4. For incremental adjustments of transition durations, you may also tap the left and right arrow marks.
5. Tap **UPDATE** to return to the **Summary** tab.

To test Transition Durations

A Transition Test allows you to test the patient's tolerance to the selected Transition Duration.

Note: The Transition Test may cause the patient discomfort.

To test **TRANSITION DURATIONS**, first navigate to the **Summary** tab of the **BrainSense Setup** workflow. See "To set up or adjust BrainSense", page 36.

1. On the **Summary** tab of the **BrainSense Setup** workflow, tap the pencil icon (next to **TRANSITION DURATIONS**.

2. Tap **TRANSITION UP TEST** (to run the test.

   Stimulation will increase from the current value to the Maximum Adaptive Amplitude using the selected Transition Up Duration.

   Notes:

   – When the Transition Test is complete, adjust stimulation back to the desired Paused Amplitude.
   – If the Transition Test was unsatisfactory, adjust the **Transition Up Duration**, and tap **TRANSITION UP TEST** again.

3. Tap **TRANSITION DOWN TEST** (to run the test.

   Stimulation will decrease from the current value to the Minimum Adaptive Amplitude using the selected Transition Down Duration.

   Notes:

   – When the Transition Test is complete, adjust stimulation back to the desired Paused Amplitude.
   – If the Transition Test was unsatisfactory, adjust the **Transition Down Duration**, and tap **TRANSITION DOWN TEST** (again.

4. Tap **UPDATE** to return to the **Summary** tab.

To pause Adaptive Therapy

Pausing Adaptive Therapy causes Adaptive Therapy to stop for an entire group, but saves all Adaptive Therapy settings until it is set to **Adapting** again.

Notes:

- The Paused Amplitude is the stimulation amplitude the patient will receive when Adaptive Therapy is Paused. The patient will receive this therapy until Adaptive Therapy is Resumed. **Setting the Paused Amplitude is necessary to ensure that patients can pause Adaptive Therapy due to stimulation-related side effects or non optimized Adaptive Therapy.** For instructions on setting the Paused Amplitude value for a group, refer to "To set up or adjust Adaptive Therapy", page 41.
- When Adaptive Therapy is set to **Paused**, stimulation can be manually adjusted on the Programming screen.
- When Adaptive Therapy is set to **Paused**, the patient can re-activate Adaptive Therapy using the patient control device. To prevent the patient from enabling Adaptive Therapy, set **BrainSense Status** to **Sensing Only** or **Off** using the dropdown list.
- **Even when Adaptive Therapy is set to Paused, the patient cannot make any adjustments to the stimulation amplitude.** To make adjustments to stimulation amplitude, the patient must switch to a group that is set to **Sensing Only** or Off. To allow adjustment of stimulation amplitude in a group that is set up for Adaptive Therapy, set **BrainSense Status** to **Sensing Only** or **Off**.

To pause Adaptive Therapy for a group, navigate to the Programming screen for a program in that group, then tap the **Adaptive Therapy** toggle switch near the top of the screen.

- **Adapting –** When the toggle switch is green (, Adaptive Therapy is active.
- **Paused –** When the toggle is gray (, Adaptive Therapy is paused.

To disable Adaptive Therapy

Quick navigation: HOME > STIMULATION > OK > Tap actively adapting program

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Tap any active program with Adaptive Therapy to proceed to the Programming screen.

1. On the Programming screen, tap the **BrainSense** tab.

2. Select “Sensing Only” or "Off" from the **BrainSense Status** dropdown list.

Notes:

- Adaptive Therapy is a hemisphere-specific feature. To disable Adaptive Therapy for the entire group, repeat this process for the other hemisphere.
- When Adaptive Therapy is disabled for a hemisphere, the patient cannot start adapting with their handset for that hemisphere.
- When Adaptive Therapy is disabled for all hemispheres, the patient can make adjustments to their stimulation amplitude, if patient limits for amplitude have been set up.
- To re-enable Adaptive Therapy, select “Adaptive” from the **BrainSense Status** dropdown list.

To turn off BrainSense

Quick navigation: HOME > STIMULATION > OK > Tap actively sensing program

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (⌂ in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Tap any active program with BrainSense to proceed to the Programming screen.

1. On the Programming screen, tap the **BrainSense** tab.
2. Select “Off” from the **BrainSense Status** dropdown list.

Notes:

- BrainSense is a hemisphere-specific feature. To turn off BrainSense for the entire group, repeat this process for the other hemisphere.
- You can turn BrainSense back on by selecting “Sensing Only” or “Adaptive” from the **BrainSense Status** dropdown list.

To remove BrainSense from a group

To remove BrainSense from a group, delete the group and reprogram that group without BrainSense. See "MANAGING GROUPS", page 28.

Changing the electrode configuration will also allow you to remove BrainSense. See "To program", page 24.

Note: If you remove BrainSense, BrainSense settings will not be saved.

About streaming of BrainSense data

The BrainSense streaming feature allows you to visualize real-time changes in the LFP power of signals during active stimulation programming in clinic. Programming parameter adjustments are available on the streaming screen, and the live physiological data can be referenced to understand the response of an LFP signal of interest to alterations in therapy settings.

Notes:

- BrainSense streaming data populates two graphs in real time:
  - **LFP Power –** LFP power in the selected frequency band, in relation to the LFP thresholds (if thresholds were captured).
  - **Amplitude –** Amplitude of stimulation (mA), in relation to stimulation limits at the time of the stream.
- To manually adjust stimulation or patient limits from the streaming screen, you must first pause Adaptive Therapy.
- To manually adjust an LFP threshold, you must first pause both Adaptive Therapy and streaming of BrainSense data.
- When the contralateral hemisphere's Sensing data is driving Adaptive Therapy in the selected hemisphere, the streaming graph will display the LFP power Sensing data from the contralateral hemisphere.

- A scrollbar is available below the graph in cases where the total amount of streaming data exceeds the current selected time duration.
- Tap the full stream button (to zoom out and display the entirety of the streaming data from the current session on the graph.

To stream BrainSense data

Quick navigation: HOME > STIMULATION > OK > Tap actively sensing program > BrainSense tab

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Tap an actively sensing program to proceed to the Programming screen.

1. On the Programming screen, tap the **BrainSense** tab.
2. Tap **START STREAMING** to begin streaming BrainSense data.
3. Tap **PAUSE STREAMING** to stop streaming.

   Notes:

   – While both streaming and Adaptive Therapy are paused, LFP Thresholds are modifiable using the adjustment flags on the graph (. You may also increase or decrease a threshold using the up and down arrows.

   – While paused, you can use the horizontal slider (at the bottom of the graph to view LFP power and amplitude values at a specific point in time.

   – While streaming is paused, tap the dropdown menu above the graph to select a time segment to display. Tap the plus and minus buttons to increase or decrease the value of the selected time segment.

   – To zoom in on the x and y-axes while streaming is paused, pinch the graph with two fingers.
4. To resume streaming, tap **RESUME STREAMING**.

To use LFP streaming data to view real-time effects of stimulation

Quick navigation: HOME > STIMULATION > OK > Tap actively sensing program > BrainSense tab

Begin on the **BrainSense** tab of the Programming screen. See "To stream BrainSense data", page 45.

1. If configured, pause Adaptive Therapy.
2. Set stimulation amplitude to 0.0 mA for 45 to 60 seconds to establish a physiologic baseline.
3. Tap **START STREAMING** to begin streaming BrainSense data.
4. Press and drag the slider (on the vertical slider bar to increase stimulation by 0.1 - 0.5 mA.

   Note: The ramp interval can be adjusted from 0.5 seconds to 10 seconds through the Settings button (on the BrainSense tab.
5. After each adjustment, stream data for 30 to 45 seconds to determine the effects of new stimulation on LFP power.
6. Explore the correlation between patient symptoms and LFP reduction.

To review BrainSense data

Use the **EVENTS** screen to review BrainSense data. See "EVENTS SCREEN", page 54.

PATIENT CHECK BATTERY REMINDER

To set the patient check battery reminder

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen. Tap any active program to proceed to the Programming screen.

1. On the Programming screen, tap the **Settings** button (in the top-right corner.
2. Tap the **Device and Session** tab.
3. Under **Device**, tap the pencil icon (under **CHECK BATTERY REMINDER**.

   Note: If the Check Battery Reminder toggle is off (, tap it to turn it on (, then tap the pencil icon (.
4. Swipe up and down on the hour and minute controls to set the patient check battery reminder.
5. Tap **UPDATE**.

MEASURING IMPEDANCE

For information on intraoperative troubleshooting related to unexpected impedance values, see "ELECTRODE IMPEDANCE TROUBLESHOOTING (INTRAOPERATIVE)", page 60.

For information on post-implant troubleshooting related to unexpected impedance values, see "ELECTRODE IMPEDANCE TROUBLESHOOTING (POST-IMPLANT)", page 61.

Use the **IMPEDANCE** screen to measure impedances to identify problems with the components of the electrical system, from the neurostimulator to the lead. Impedance measurements performed at the beginning of the session may also help interpreting diagnostic data collected by the device since the previous session.

Impedance measurements verify the integrity of the component connections (eg, lead, extension, neurostimulator). Measuring impedances may help identify potential circuit problems in the system (eg, lead breakage, short circuit, open circuit).

Notes:

- A significantly high impedance value may indicate a fractured lead conductor, a loose setscrew, etc.
- A significantly low impedance value may indicate shorted conductors, a break in the lead insulation, etc.

The application prompts an impedance test at the start of each new session. During a session, impedance can be measured at any time. For more information, refer to "To perform an electrode impedance test", page 47.

Impedance Summary tab

The **Summary** tab on the **IMPEDANCE** screen includes a visual representation of the impedance values on each of the lead electrodes.

Electrodes are individual contacts on the distal end of the lead.

After an electrode impedance measurement has been taken, inactive electrodes are represented by rectangles (or or).

To perform an electrode impedance test

There are options when you run an electrode impedance test:

- **Single amplitude (0.4 mA or 1.0 mA)**

  If you select a single amplitude, that amplitude will be used for the duration of the test.

- **Automatic increase**

  If you select **Automatic increase**, the system will automatically start with 0.1 milliamps for the test. The system may automatically increase the pulse width to 450 µs and/or increase the amplitude to 0.4 milliamps to complete the test.

  Note: If the Automatic increase results in high impedance levels, consider running a Single amplitude test to see if results normalize.

The following table captures the potential combinations of stimulation parameters used during the impedance test.

Intensity	Pulse width	Rate
0.1 mA	80 µs[a]	100 Hz
0.4 mA	80 µs	100 Hz
1.0 mA	80 µs	100 Hz

[a] If impedance is measured as higher than normal, a pulse width of 450 µs is used.

Quick navigation: HOME > IMPEDANCE > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **IMPEDANCE** and proceed to the **IMPEDANCE** screen.
2. Tap the **Electrode** tab.
3. Tap the **MEASURE ELECTRODE IMPEDANCE** button (.
4. Follow the on-screen prompts. When the impedance measurement is complete, the results appear on the **IMPEDANCE** screen (Figure 8).

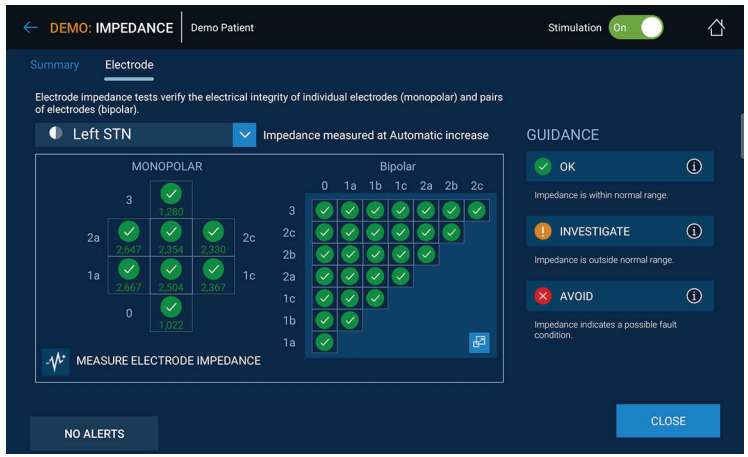

Figure 8. Electrode impedance results screen (directional lead shown, post-test).

5. Review the results.

   Notes:

   – Refer to the descriptions under **GUIDANCE** for more information on the different active electrode icons. Tap the descriptions for more information.
   – When using two leads with one neurostimulator, you can use the dropdown list to select the other lead.
   – For more information on intraoperative troubleshooting, refer to "To troubleshoot intraoperatively using electrode impedance measurements", page 60.

– For more information on post-implant troubleshooting, refer to "To troubleshoot post-implant using electrode impedance measurements", page 61.

MRI ELIGIBILITY OF THE DBS SYSTEM

About MRI eligibility and MRI mode

Refer to the “MRI Guidelines for Medtronic deep brain stimulation systems” instructions for use for the MRI conditions and MRI-specific contraindication, warnings, and precautions for conducting an MRI scan.

Always obtain the latest MRI guidelines. Refer to the contact information at the back of this manual, or go to www.medtronic.com/mri.

The **MRI ELIGIBILITY** workflow can be used to determine MRI eligibility, to view an MRI report, and to enter a neurostimulator into MRI mode.

MRI mode persists beyond a single programming session. If you exit the app without tapping **EXIT MRI MODE**, the neurostimulator will remain in MRI mode. When connected to a neurostimulator in MRI mode, the app will open to the **MRI MODE ACTIVE** screen instead of the **HOME** screen.

To check MRI scan eligibility and enter MRI mode

When using the clinician tablet to confirm scan eligibility, an MRI eligibility report must be generated for each patient. If a patient has more than one neurostimulator, an MRI eligibility report must be generated for each neurostimulator. Scan eligibility is used to show which set of conditions and settings listed in the MRI Guidelines must be used.

The results for each neurostimulator must be sent to the patient’s MRI facility before the scheduled MRI scan.

Quick navigation: HOME > MRI ELIGIBILITY > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **MRI ELIGIBILITY** and proceed to the **MRI ELIGIBILITY** workflow.
2. On the **CONFIRM SETTINGS** screen, review system settings.

   Note: If information is incorrect or incomplete, use the **GO TO** (buttons to navigate to specific screens in the **SETUP** workflow.
3. Tap **CONFIRM** to confirm settings and continue.

   Note: If you have not yet run an impedance test in this programming session, you will be prompted to run an impedance test. The impedance test is required to continue with the **MRI ELIGIBILITY** workflow. Follow the on-screen prompts until you reach the **SYSTEM ELIGIBILITY** screen.
4. On the **SYSTEM ELIGIBILITY** screen, review the MRI scan eligibility factors for the patient's DBS system.

   Note: The app will indicate which factors meet eligibility requirements (, and which factors currently restrict MRI scan type eligibility (.
5. Tap **NEXT** to continue.

   Note: If eligibility cannot be determined, refer to the "MRI Guidelines for Medtronic deep brain stimulation systems" instructions for use manual for information on next steps.
6. On the **THERAPY SETTINGS** screen, select the preferred available stimulation option for use during the MRI scan.

   Notes:

   – Stimulation off is always available. If any groups are entirely bipolar, they will also be available.
   – If the active group is among the options, it will be the default selection.
   – If the active group is unipolar, the default selection will be **Stimulation off**.
   – Prior to entering MRI mode, you can tap **CLOSE** in the bottom-right corner to return to the **HOME** screen without making changes to stimulation.
7. If desired, tap **VIEW MRI REPORT** to open an MRI Eligibility Report. This action will take you out of the programmer application. The programmer app will run in the background and your session data will remain intact.

   Note: You can also open and view an MRI Eligibility Report while in MRI mode.
8. Tap **ENTER MRI MODE** to enter MRI mode with the selected stimulation option.

   Note: Entering MRI mode will automatically turn off BrainSense. Exiting MRI mode will automatically resume BrainSense.

To exit MRI mode, tap **EXIT MRI MODE** in the bottom-right corner of the **MRI MODE ACTIVE** screen.

Interpreting MRI eligibility results

On the **MRI MODE ACTIVE** screen, you will see one of three possible eligibility outcomes, with icons and symbols. Explanations of the outcomes and their icons are described in Table 7.

Table 7. MRI eligibility icons

Icons shown	Explanation
	Full-body scan eligible — The implanted neurostimulation system is eligible to have MRI scans of any part of the body, including a head scan, using these specific conditions. The MRI clinician must consult the MRI guidelines for those conditions.
	Head scan eligible with transmit/receive head coil — The implanted neurostimulation system is eligible for MRI scans of the head only using an RF transmit/receive head coil and under

Table 7. MRI eligibility icons (continued)

	other specific conditions. The MRI clinician must consult the MRI guidelines for those conditions.
	The neurostimulation system MRI scan eligibility cannot be confirmed — The MRI clinician must consult the MRI guidelines to determine how to proceed or contact Medtronic Technical Support.

If MRI eligibility cannot be determined, check the following:

- Are the system components captured correctly?
- Is there an impedance issue? If so, refer to "To troubleshoot intraoperatively using electrode impedance measurements", page 60 for troubleshooting information.

If MRI eligibility still cannot be determined, it is because one or more factors cannot be determined to be MRI eligible by the clinician programmer application. Eligibility can also be checked using the MRI Eligibility Sheet. Refer to the “MRI Guidelines for Medtronic deep brain stimulation systems” instructions for use manual.

Viewing the MRI eligibility report

The application can generate a report that can be viewed, printed, and used as a communication to the radiology staff.

The report includes the following information:

- The date the MRI eligibility check was performed
- The eligibility results, including the type of scan that is eligible

To view the MRI eligibility report

There are two ways to view an MRI eligibility report.

- On the **THERAPY SETTINGS** screen or on the **MRI MODE ACTIVE** screen, tap the **VIEW MRI REPORT** button. The report will open in a separate program outside of the clinician programmer application.
- Navigate to the **Reports** screen. See "To view, share, download, or delete an MRI eligibility report", page 50.

To view, share, download, or delete an MRI eligibility report

MRI eligibility reports are stored on the clinician tablet. These reports can be accessed and used during the current session or referenced at a later time.

MRI eligibility reports can only be created using the MRI Eligibility workflow. See "MRI ELIGIBILITY OF THE DBS SYSTEM", page 48.

Note: The date and time of the MRI eligibility determination is located at the top of the MRI eligibility report.

1. On the **HOME** screen, tap the Menu button ().
2. Tap **Reports**.
3. Use the dropdown list to select **MRI Report**.
4. Optional) Filter using a date range:
   a. Enter the start and end dates using the calendar control.
   b. To dismiss the calendar control, tap anywhere outside of the calendar.
   c. Tap **FILTER**.
5. Find and tap the desired report from the scrollable list. The most recent report appears at the top.
6. Tap one of the buttons shown in Table 8.

Table 8. Report buttons and definitions

Button or icon	Definition
	View button – to view the report. **Note:** This action will take you out of the programmer application. The programmer app will run in the background and your session data will remain intact.
	Share button – to send the report to another app or destination. **Note:** This action will take you out of the programmer application. The programmer app will run in the background and your session data will remain intact.

Table 8. Report buttons and definitions (continued)

Button or icon	efinition
	Download button – to download and save the report on the clinician tablet.
	Delete button – to delete the report.

To exit MRI mode

MRI mode persists beyond a single programming session. If you exit the app without tapping **EXIT MRI MODE**, the neurostimulator will remain in MRI mode settings. The app will open to the **MRI MODE ACTIVE** screen instead of the **HOME** screen.

To exit MRI mode, tap **EXIT MRI MODE** in the bottom-right corner of the **MRI MODE ACTIVE** screen.

REPLACING A NEUROSTIMULATOR

When available, the **REPLACEMENT** workflow allows you to transfer existing neurostimulator settings to a new neurostimulator.

In some of these situations, the **REPLACEMENT** workflow sets amplitude to zero for all groups and programs. See Table 9 for specific outcomes.

Table 9. Outcomes for REPLACEMENT workflow

Source	Destination	Outcome
Percept RC	Percept RC	Transfers settings
	Percept PC	Not available
	Activa RC	Not available
	Activa PC	Not available
	Activa SC	Not available
Percept PC	Percept RC	Transfers settings
	Percept PC	Transfers settings
	Activa RC	Not available
	Activa PC	Not available
	Activa SC	Not available
Activa RC	Percept RC	Transfers settings, but amplitude set to zero
	Percept PC	Transfers settings, but amplitude set to zero
	Activa RC	Transfers settings
	Activa PC	Transfers settings, but amplitude set to zero
	Activa SC	Not available
Activa PC	Percept RC	Transfers settings, but amplitude set to zero
	Percept PC	Transfers settings, but amplitude set to zero

Table 9. Outcomes for REPLACEMENT workflow (continued)

Source	Destination	Outcome
	Activa RC	Transfers settings, but amplitude set to zero
	Activa PC	Transfers settings
	Activa SC	Not available
Activa SC	Percept RC	Transfers settings, but amplitude set to zero
	Percept PC	Transfers settings, but amplitude set to zero
	Activa RC	Not available
	Activa PC	Not available
	Activa SC	Transfers settings

Quick navigation: HOME > REPLACEMENT > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **REPLACEMENT** and proceed to the **REPLACEMENT** screen.
2. Tap the **SEARCH FOR NEW DEVICE** button (and follow the on-screen prompts.
3. Position the communicator over the new neurostimulator.
4. Tap the **TRANSFER SETTINGS** button (See Table 9 for specific outcomes and considerations.

   Notes:

   – Always review group and program settings on the new neurostimulator for completeness after transferring settings. In some cases, certain group and program settings are intentionally not transferred.

   – Additionally, if you transferred settings from an existing Percept neurostimulator to a new Percept neurostimulator, confirm that the BrainSense parameters are appropriate.
5. Tap the **End Session** button (.

NEUROSTIMULATOR BATTERY

Checking the neurostimulator battery

Neurostimulator battery information is displayed under **DEVICE** on the **HOME** screen. For more information on the **HOME** screen, see "PROGRAMMER SETUP", page 12.

Non-rechargeable neurostimulator ONLY: Non-rechargeable neurostimulator battery level is displayed in percentage and one of four possible states (Table 10).

Table 10. Non-rechargeable battery states

Percentage (eg, 75%)	The neurostimulator battery is good and no action is needed.
Estimated Battery Life Remaining	Estimate generated based on the last seven (7) days of battery usage. Monitor this value to determine how stimulation parameters affect battery life. Changes to stimulation, whether made by the clinician, the patient, or Adaptive Therapy, are reflected in the Estimated Battery Life Remaining value.
ERI (Elective Replacement Indicator) **REPLACEMENT NEEDED**	**Neurostimulator battery is low. Schedule replacement to avoid loss of therapy.** **Note:** For patients who use high levels of stimulation, end of service could occur in as little as 10 weeks after the neurostimulator reaches ERI. Patients who use lower levels of stimulation will have more time before reaching end of service.
ERI (Elective Replacement Indicator) **REPLACEMENT RECOMMENDED**	**The recommended service life has been exceeded. Schedule a replacement to avoid potential loss of therapy.** When the neurostimulator reaches 11 years of service, replacing the neurostimulator is recommended.
END OF SERVICE **EOS)**	**The neurostimulator needs to be replaced.** The neurostimulator has reached the end of its service life and is no longer delivering stimulation.

Rechargeable neurostimulator ONLY: Rechargeable neurostimulator battery level is estimated to the nearest 10 percent value (e.g., 10%, 20%, 30%, etc.) and is displayed in one of two possible states (Table 11).

Table 11. Rechargeable battery states

Battery state	Description and required action
Percentage (eg, 80%)	The neurostimulator battery is good and no action is needed.
ERI (Elective Replacement Indicator) **REPLACEMENT RECOMMENDED**	**The recommended service life has been exceeded. Schedule a replacement to avoid potential loss of therapy.** When the neurostimulator reaches 15 years of service, replacing the neurostimulator is recommended.

EVENTS SCREEN

The **EVENTS** screen allows you to view historical data related to BrainSense, events, usage, and battery recharge.

The **EVENTS** screen is divided into six tabs:

- **Summary –** A high-level view of event markers and other changes. See "Summary", page 54.
- **Timeline –** A view of LFP data and stimulation over time. The Timeline tab also displays the patient's use of event markers and stimulation adjustment. See "Timeline", page 55.
- **LFP Chart –** A view of the time spent above, below, and between thresholds. See "LFP Chart", page 56.
- **Event LFP Snapshots –** A view of LFP snapshots of events that the patient recorded. See "Event LFP Snapshots", page 56.
- **Device Usage** – A view of the patient's use of groups. See "Device Usage", page 56.
- **Battery Recharge –** For the Percept RC neurostimulator, view information for each recharging session over time, such as the recharge duration and battery level at start and end of recharge. See "Battery Recharge", page 56.

To access the EVENTS screen

Quick navigation: HOME > EVENTS > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **EVENTS** and proceed to the **Summary** tab of the **EVENTS** screen.
2. Use the tabs near the top of the screen to switch between tabs.

Summary

The **Summary** tab on the **EVENTS** screen displays a high-level view of event and BrainSense data available for the patient. It also allows you to set up or edit patient event names.

You can use the dropdown lists to select what data to view, and over which range of time.

To set up or edit patient event names

Note: You can also edit patient event names from the Programming screen. Tap the Settings button ( ) on the Programming screen, then tap the **Device and Session** tab. Under **Patient Events**, tap on the pencil icon ( ) for an event to edit that event name.

1. Tap the pencil icon (.
2. For each of the four patient event types available, tap the text field and use the on-screen keyboard to enter a name for the patient event.

   Note: The patient will see the event names on the handset when recording an event.
3. Use the **ENABLE** checkbox next to each event to toggle whether that event type is available to the patient.
4. Use the **LFP CAPTURE** checkbox next to each event to toggle whether an LFP snapshot is captured when the patient records that event type.

   Note: The LFP snapshot will only be captured if the patient is using a BrainSense-enabled group at the time the event is recorded.
5. If the diagnosis that you selected in the **SETUP** workflow allows it, you can use the **CYCLING** checkbox next to each event to toggle whether the neurostimulator restarts the stimulation cycle when the patient records that event type.
6. Tap **UPDATE** to return to the **Summary** tab.

Timeline

The **Timeline** tab on the **EVENTS** screen (Figure 9) displays a detailed historical timeline of events, as well as changes in stimulation made by the patient such as turning stimulation on or off, changing groups, beginning or ending a recharging session, and entering or exiting MRI mode.

If BrainSense is enabled, the line graph shows the amplitude of stimulation and the power of the LFP signal, in the selected frequency band, over time.

Reviewing timeline statistics may inform on the patient's use of event markers, or the use of the patient control device for adjusting stimulation.

Notes:

- Areas filled with columns of Xs denote time spent in a clinician programming session. Brief clinician programming sessions may not appear.
- When in MRI mode, event markers will be recorded, but LFP signal data will be unavailable because BrainSense is automatically disabled while in MRI mode.
- During a recharging session, LFP signal data will be unavailable, because BrainSense is automatically disabled during a recharging session. LFP signal data will be automatically enabled when the recharging session ends.
- LFP signal data will be paused during impedance tests, and the data will automatically resume when the impedance test is complete.
- For the Percept RC neurostimulator, LFP signal data will be unavailable if the rechargeable neurostimulator battery is depleted and is unable to maintain a charge. A green X is shown on the graph to indicate when therapy was unavailable. Tap the X to see details.
- For the Percept RC neurostimulator, up to 35 days of LFP and stimulation amplitude data can be displayed on the timeline. For the Percept PC neurostimulator, up to 60 days of LFP and stimulation amplitude data can be displayed on the timeline.

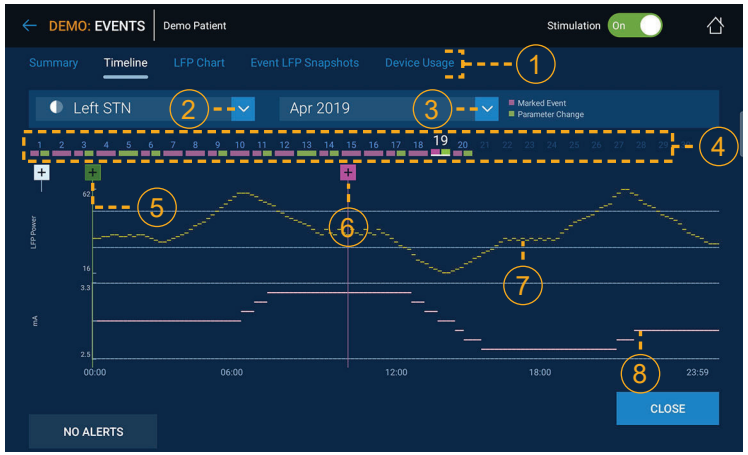

Figure 9. The Timeline tab of the EVENTS screen.

①	**Navigation tabs –** Tap to view another screen.
②	**Lead location dropdown list –** Tap to select between lead locations, if multiple leads are set up.
③	**Month dropdown list –** Tap to select a month to view.
④	**Date selection row –** Each number represents a date of the month. Tap a number to view that date. Swipe the screen to the left or right to view the next or previous day.
⑤	**Stimulation adjustment by patient (example) –** A green plus, if one is shown, indicates a time when the patient adjusted their stimulation. Tap the plus to see details.
⑥	**Event logged by patient (example) –** A pink plus, if one is shown, indicates a time when the patient logged an event. Tap the plus to see details.
⑦	**LFP signal –** A graphical representation of the power of the LFP signal, within the selected frequency band, over time. ■ The LFP signal is shown relative to LFP thresholds, if such thresholds were set.

(continued)

	■ LFP data is only shown for time periods when BrainSense was enabled. ■ When BrainSense is enabled, LFP data is recorded in ten-minute increments. The average value is calculated and assigned to each ten-minute increment.
⑧	**Amplitude –** A graphical representation of the amplitude of stimulation over time. ■ The amplitude is only shown for times when BrainSense was enabled. ■ The color of the line changes when Adaptive Therapy is toggled between **Adapting** (pink) and **Paused** (orange). ■ Amplitude is recorded in ten-minute increments. The average value is calculated and assigned to each ten-minute increment.

LFP Chart

The **LFP Chart** tab on the **EVENTS** screen uses a bar graph to display the percentage of time a patient's LFP was measured as above the upper threshold, below the lower threshold, or between the two thresholds (if applicable).

Notes:

- Use the dropdown lists to select the lead location, the group, and the timeframe to view.
- Tap the left (< and right (> arrow buttons to view earlier and later timeframes.
- The amplitude value listed below each bar in the graph represents the average amplitude used for that duration of time.

Event LFP Snapshots

The **Event LFP Snapshots** tab on the **EVENTS** screen uses a graph to display LFP snapshots of events that the patient recorded.

An Event LFP Snapshot is a recorded moment in time, showing the magnitude of the LFP signal over a range of frequencies.

Only events with the **LFP** checkbox checked in the **CONFIGURE PATIENT EVENTS** menu from the **Summary** tab (at the time the patient recorded the event) will be included in this view.

Notes:

- Use the dropdown lists to select the lead location, the timeframe to view, and which event types to display.
- Tap **FILTER** to select which event type(s) to view.
- Use the checkboxes to toggle inclusion of individual events.
- Use the horizontal slider (to view the LFP magnitude over the full range of LFP frequency on the graph.
- Tap the **CLEAR SELECTION** button to clear all events from the displayed graph.

Device Usage

The **Device Usage** tab on the **EVENTS** screen uses a bar graph to display the use of groups by the patient over time, represented in percentages. Reviewing device usage statistics may inform on the patient's use of groups, including ability to change groups.

Notes:

- You can also access the **Device Usage** tab directly from the **HOME** screen by tapping the menu button (and then tapping **Usage**.
- Use the dropdown list to select the timeframe to view.
- Tap the left (< and right (> arrow buttons to view earlier and later timeframes.

Battery Recharge

The **Battery Recharge** tab on the **EVENTS** screen shows the following information for each recharging session over time:

- Duration of the recharging session.
- Recharge coupling.
- Battery level at start and end of the recharging session.
- Average battery level at the end of a recharging session.
- Average duration of a recharging session.
- Average recharge interval.

Reviewing recharge statistics may inform on the patient's recharge behavior, including ability to recharge properly and efficiently.

Notes:

- Each bar on the graph represents a recharging session. The date is displayed along the bottom of the graph.
- The bottom of each bar indicates the battery level at the start of the recharge, and the top of each bar indicates the battery level at the end of the recharge. All displayed values are rounded to the nearest 10 percent value (e.g., 10%, 20%, 30%, etc.).
- The duration of the recharge is listed within each bar.
- Recharge coupling represents the signal strength of the recharging session.
- If signal strength is fair, discuss recharger positioning with the patient.
- Adaptive Therapy can influence recharge intervals. Monitor the average recharge interval to determine if Adaptive Therapy should be continued.

ANATOMY DATA

About anatomy data

Anatomy data can be imported to provide anatomical context for programming.

△ **Caution:** All DBS programming decisions remain in the programming clinician's judgment. All programmed settings should be screened and selected based on patient physiological response. Reliance on anatomy data in place of clinical judgment could result in excessive stimulation, inadequate stimulation, or stimulation to an unintended target.

To import anatomy data

Quick navigation: HOME > STIMULATION > OK > Tap active program on GROUPS screen

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program.

   Note: Only one group can be active at a time. To adjust an inactive program, tap the group that contains the program you wish to adjust.
3. Tap the plus next to the anatomy button (shown on the Programming screen.

   Note: The anatomy button will only appear on the Programming screen if anatomy data has been made available on your network.
4. Tap the **SELECT** button next to the correct patient.

Notes:

- Patient information recorded in the **SETUP** workflow is used to search for anatomy data. When multiple results are displayed, ensure that the correct patient is selected.
- If using a directional lead, you may be prompted to set or confirm lead orientation. For more information on orienting a directional lead, refer to "To orient a directional lead", page 26.

To view anatomy data

Once anatomy data has been successfully imported, you can customize the display of the data.

1. Tap the arrow next to the anatomy button (shown on the Programming screen. A dropdown list will appear.
2. Tap the checkbox next to each item to select whether to display it.

   Note: An asterisk next to a structure indicates that it is a custom structure.
3. Tap anywhere outside the dropdown list to return to the Programming screen.

ENDING A SESSION

The **END SESSION** workflow allows you to review any changes you made during the session, enter additional notes, and end the session.

Note: You can also end a session by tapping the **End Session** button (in the top-right corner of the **HOME** screen. This method will not allow you to review initial and final programming values prior to ending the session.

Quick navigation: HOME > END SESSION > OK

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **END SESSION** and proceed to the **END SESSION** screen.
2. Review the information displayed on the **END SESSION** screen.

   Notes:

   - Swipe up and down on the screen to scroll.
   - Information is displayed with initial settings on the left, and final settings on the right.
3. While on the **END SESSION** screen, you have the option to perform any of the following tasks:
   a. If you wish to undo programming changes made during this session, tap the **UNDO** button (. A window will appear asking for confirmation.
   b. Throughout the **END SESSION** screen, you can use shortcut buttons (to go directly to other sections of the app, where you can make adjustments before returning to the **END SESSION** screen.
   c. If you wish to add any free-text notes, tap the **CLINICIAN NOTES** button (.

4. Tap the **END SESSION** button to end the session and return to the title screen.

INFORMING THE PATIENT

Before the patient goes home with their implanted system, educate and provide the patient with the following information:

- How to turn the patient control device on or off.
- How to connect the patient control device to the neurostimulator, including how to avoid sources of electromagnetic interference EMI).
- How to turn stimulation on and off.
- How to adjust their stimulation within patient limits, if patient limits were set.
- How to correctly check and interpret neurostimulator battery status.
- How to recharge the neurostimulator battery, if applicable.
- How to correctly check and interpret patient control device battery status.
- How to set preferences on the patient control device.
- How to change groups, if applicable.
- How to record events, if applicable.
- How to return unwanted handsets to Medtronic for disposal, to ensure patient privacy is protected.
- How to pause Adaptive Therapy, if Adaptive Therapy was enabled.

ELECTRODE IMPEDANCE TROUBLESHOOTING INTRAOPERATIVE)

Use the steps below when using electrode impedance measurements to troubleshoot the system intraoperatively.

For further assistance with troubleshooting using impedance measurements, contact Medtronic using the information on the back cover of this manual. In the U.S., call 1-800-707-0933 for Medtronic Technical Services.

Electrodes are individual contacts on the distal end of the lead.

When an electrode impedance measurement is performed, impedances are measured between each electrode combination.

Once the electrode impedance measurement is performed, the results can be viewed during the programming session by navigating to the **IMPEDANCE** screen. For more information on measuring impedance, refer to "MEASURING IMPEDANCE", page 46.

You can also view or print the Session Report, which shows the impedance measurements. Refer to "REPORTS", page 63.

To troubleshoot intraoperatively using electrode impedance measurements

1. Analyze electrode impedance patterns. An outlier measurement may indicate an issue with a setscrew or wire. Tighten setscrew(s) and measure impedance again.

   For more information about measuring electrode impedance, refer to "To perform an electrode impedance test", page 47.
2. If high tissue impedance is suspected, apply stimulation for a few minutes and measure impedance again.
3. If a trend towards normal impedance range is not observed, disconnect the lead from the extension and use a compatible test cable or screening cable to test the impedance of the lead alone.
   - If the impedance value is less than 2,000 Ω (1x4 monopolar) or 4,000 Ω (1x4 bipolar) or 8,000 Ω (directional monopolar) or 10,000 Ω (directional bipolar), then the lead is intact.
   - If the impedance value is greater than 2,000 Ω (1x4 monopolar) or 4,000 Ω (1x4 bipolar) or 8,000 Ω (directional monopolar) or 10,000 Ω (directional bipolar), visually or fluoroscopically inspect the lead for damage.

△ **Caution: For SenSight test cable only —** If higher than expected impedance values are observed, ensure that the lead test cable is attached to the lead correctly and perform the following steps to improve the lead test cable connection:

- Maintain the lead position.
- Maintain the test cable connection. Do not open the test cable connector.
- Rotate the test cable around the lead approximately a quarter turn (90 degrees), then back to the original position before measuring impedances.

4. If lead is intact, reconnect the lead to the extension and use a compatible test cable or screening cable to test the impedance of the lead and extension together.
   - If the extension impedance value is below 2,000 Ω (1x4 monopolar) or 4,000 Ω (1x4 bipolar) or 8,000 Ω (directional monopolar) or 10,000 Ω (directional bipolar), the extension is intact.
   - If the extension impedance value exceeds 2,000 Ω (1x4 monopolar) or 4,000 Ω (1x4 bipolar) or 8,000 Ω (directional monopolar) or 10,000 Ω (directional bipolar), visually or fluoroscopically inspect the extension and extension connection for damage.
   - If two extensions are being used, swap the extensions with one another and measure impedance again to see if the out-of-range impedance value is specific to one of the extensions. If the out-of-range impedance value is specific to one of the extensions, consider replacing that extension.

△ **Caution: For SenSight test cable only —** If higher than expected impedance values are observed, ensure that the

extension test cable is attached to the extension correctly and perform the following steps to improve the extension test cable connection:

- Maintain the extension position.
- Maintain the test cable connection. Do not open the test cable connector.
- Rotate the test cable around the extension approximately a quarter turn (90 degrees), then back to the original position before measuring impedances.

5. Reconnect the neurostimulator to the lead and extension. Ensure the neurostimulator is in the pocket and retest the system. If the impedance value remains high, visually or fluoroscopically inspect the neurostimulator-to-extension connection and the neurostimulator connector block for damage.
   - If the neurostimulator impedance value is below 2,000 Ω 1x4 monopolar) or 4,000 Ω (1x4 bipolar) or 8,000 Ω directional monopolar) or 10,000 Ω (directional bipolar), the neurostimulator is intact.
   - If the neurostimulator impedance value exceeds 2,000 Ω 1x4 monopolar) or 4,000 Ω (1x4 bipolar) or 8,000 Ω directional monopolar) or 10,000 Ω (directional bipolar), visually or fluoroscopically inspect the neurostimulator and neurostimulator-extension connection for damage.
   - If two neurostimulators are being used, swap the neurostimulators with one another and measure impedance again to see if the out-of-range impedance value is specific to one of the neurostimulators. If the out-of-range impedance value is specific to one of the neurostimulators, consider replacing that neurostimulator.
6. If the previous steps fail to reveal the underlying issue, assess whether it is possible to achieve therapy without using the electrode with high impedance.
7. If all other troubleshooting measures fail, replace the neurostimulator as needed.

ELECTRODE IMPEDANCE TROUBLESHOOTING (POST-IMPLANT)

Use the steps below when using electrode impedance measurements to troubleshoot the system post-implant.

For further assistance with troubleshooting using impedance measurements, contact Medtronic using the information on the back cover of this manual. In the U.S., call 1-800-707-0933 for Medtronic Technical Services.

Notes:

- Electrodes are individual contacts on the distal end of the lead.
- When an electrode impedance measurement is performed, impedances are measured between each electrode combination.
- Once the electrode impedance measurement is performed, the results can be viewed during the programming session by navigating to the **IMPEDANCE** screen.
- When the electrode configuration is changed, impedance results are cleared.
- For more information on measuring impedance, refer to "MEASURING IMPEDANCE", page 46.
- You can also view or print the session report, which shows the impedance measurements. Refer to "REPORTS", page 63.

To troubleshoot post-implant using electrode impedance measurements

⚠ **Warning:** When troubleshooting issues related to impedance measurements, follow these instructions correctly and completely to identify and resolve the issue.

- Mistaking an undamaged component as damaged could result in unnecessary surgical revision.
- Failure to identify a damaged component could result in unresolved intermittent or loss of stimulation.

For more information about measuring electrode impedance, refer to "To perform an electrode impedance test", page 47.

If electrode impedance values are greater than 40,000 Ω:

An impedance value above 40,000 Ω is the result of an open circuit. The following steps may help identify from where the underlying issue originates.

1. Confirm that the implanted component models match what is shown on the programmer application.
   a. Consult the patient's medical records for correct component information.
   b. X-ray may also be used to aid in component identification.
2. Ensure the neurostimulator has not migrated away from the pocket.
3. Check for loose connections. Palpate along the system as needed.
4. Fluoroscopically inspect the lead-extension and neurostimulator-extension connections for damage.
5. Consider using x-ray to identify an issue within components.
6. If the previous steps fail to reveal the underlying issue, assess whether it is possible to achieve therapy without using the electrode with high impedance.

If the high-impedance electrodes are necessary for programming, revision surgery may be needed.

If electrode impedance values are between 2,000 Ω and 40,000 Ω (1x4 monopolar)

OR

4,000 Ω and 40,000 Ω (1x4 bipolar)

OR

8,000 Ω and 40,000 Ω (directional monopolar)

OR

10,000 Ω and 40,000 Ω (directional bipolar):

The following steps may help identify the underlying issue.

1. Analyze impedance patterns on the **Electrode** tab of the **IMPEDANCE** screen. For more information about measuring electrode impedance, refer to "To perform an electrode impedance test", page 47.
   a. If all monopolar impedance values are similar, and all bipolar impedance values are similar, this could be indicative of high tissue impedance.
   b. If the suspect electrode is not in use, apply stimulation for a few minutes using the suspect electrode.
   c. Measure impedance again to see if impedance results have improved.
2. Check for loose connections. Palpate along the system as needed.
3. Fluoroscopically inspect the lead-extension and neurostimulator-extension connections for damage.
4. Consider using x-ray to identify an issue within the components.
5. If the previous steps fail to reveal the underlying issue, assess whether it is possible to achieve therapy without using the electrode with high impedance.

If the high-impedance electrodes are necessary for programming, revision surgery may be needed.

If impedance values are less than 250 Ω (1x4 lead)

OR

If impedance values are less than 350 Ω (directional lead):

A low impedance value is likely the result of a damaged wire or breached insulation. The following steps may help identify the underlying issue.

1. Confirm that the implanted component models match what is shown on the programmer application.
   a. Consult the patient's medical records for correct component information.

b. X-ray may also be used to aid in component identification.

2. Determine the location of the damaged component. Each component has a known maximum impedance (Table 12), which may help to identify which component is damaged.

   Example: If the impedance is 100 Ω, the issue is likely with the lead because the components nearer to the neurostimulator (extensions or pocket adaptors) have lower maximum impedance values. If there had been a break in the extension or pocket adaptor, the measurement would result in an impedance value lower than the maximum for those components.

Table 12. Component specific maximum impedance in ohms

Component Model and type	Maximum impedance
7482, 7482A, 7483 extensions	7 Ω
37085, 37086 extensions	38 Ω
B34000 extension	47 Ω
64001, 64002 pocket adaptors	50 Ω
3387, 3387S, 3389, 3389S leads	<100 Ω
3391, 3391S leads	200 Ω
B33005, B33015 leads	100 Ω

3. If the previous steps fail to reveal the underlying issue, assess whether it is possible to achieve therapy without using the electrode with low impedance.

If the low-impedance electrodes are necessary for programming, revision surgery may be needed.

REPORTS

About reports

Note: Reports and other patient data may be automatically deleted after a specified number of days, per default settings. For more information on adjusting or disabling this auto-delete feature, refer to "Patient data auto-delete feature", page 64.

The **REPORTS** screen allows you to view multiple types of reports:

- **Session Report –** contains information specific to a programming session.

  Note: Select the **Offline Data Viewer** button (☰) to review BrainSense data when not in session. Refer to Table 13 for more information.
- **Patient Report –** contains some of the contents of a session report. This report is intended to be given to the patient for their records.
- **MRI Report –** contains MRI eligibility information related to an individual neurostimulator. Refer to the “MRI Guidelines for Medtronic deep brain stimulation systems” instructions for use for information on generating an MRI report.
- **Medtronic Data Report –** contains device, system, and telemetry information for use by Medtronic. This report may be used when a problem is encountered and assistance from Medtronic is needed. Refer to “To create a Medtronic data technical) report” for details on how to generate a Medtronic data report.
- **Export Json Session Data –** contains a JSON file of session data that can be used for further analysis.

To view, share, download, or delete a report

The **REPORTS** screen also allows you to share, download, or delete these reports.

Quick navigation: Open DBS app > REPORTS button

Or

HOME > Menu button (> Reports

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. Tap the menu button (in the top-left corner and select **Reports**.
2. From the **REPORTS** screen, use the dropdown list to select the desired report type.
3. Optional) Filter using a date range:
   a. Enter the **START DATE** and **END DATE** using the calendar control.
   b. To dismiss the calendar control, tap anywhere outside of it.
   c. Tap **FILTER**.
4. Find and tap the desired report from the scrollable list. The most recent reports appear at the top.
5. Tap one of the buttons shown in Table 13.

Table 13. Report buttons and options

Button or icon	Definition
	Offline Data Viewer button – to review BrainSense data when not in session. **Note:** Information displayed is determined by selections made during session.
	View button – to view the report. **Notes:** ■ This action will take you out of the programmer application. The programmer app will run in the background and your session data will remain intact. ■ Export Session Data reports, Export Session Annotations reports, and Export Json Session Data reports cannot be viewed.

Table 13. Report buttons and options (continued)

Button or icon	Definition
	Share button – to send the report to another destination, send via email, or print the report via tablet-provided printing options. **Note:** This action will take you out of the programmer application. The programmer app will run in the background and your session data will remain intact.
	Download button – to download and save the report on the clinician tablet.
	Delete button – to delete the report.

Patient Data Service app

The Patient Data Service app can also be used to access reports for all patients whose Medtronic devices have been programmed using any clinician programmer application on the same clinician tablet.

Patient data auto-delete feature

The Patient Data Service app can be used to adjust (or disable) the auto-delete feature, which automatically deletes patient data (after it has been compiled into reports) after a designated amount of time.

Note: The auto-delete feature is enabled by default, with a preset amount of time. To prevent unwanted deletion of data, check your auto-delete settings and edit them as needed.

Within the Patient Data Service app, tap the Settings button (to change or disable the auto-delete feature.

ABOUT SCREEN

The **ABOUT** screen provides the following information and capabilities:

- System component information, such as model numbers, serial numbers, version numbers, etc., for the device (INS), recharger, tablet, clinician app, controller, and communicator.
  - Communicator information is for the most recent communicator to have paired to the tablet.
  - Recharger (if shown) and patient control device information is for the most recent recharger and patient control device to have communicated with the neurostimulator.
- Ability to change the date and time for the INS.
- Ability to change the INS implant date.
- Ability to generate a Medtronic data report.
- Trademarks and licenses information.

To access the ABOUT screen

Quick navigation: HOME > Menu button (> About

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. Tap the menu button (in the top-left corner and select **About**.
2. Tap the tab for the component information you want to view.

To change the neurostimulator date and time

On the **Device** tab, use the **TIME SOURCE** dropdown list to select the time source.

- **Tablet:** Automatically uses the date and time displayed on the tablet as the time source for the neurostimulator. After picking this option, tap the **UPDATE DEVICE TIME** button (.
- **Manual:** Allows you to manually adjust the date and time for the neurostimulator.

To change the implant date

Tap the **IMPLANT DATE** text field to adjust the implant date. After selecting the implant date, tap the **DONE** button to close the calendar menu.

To create a Medtronic data (technical) report

Tap the **CREATE MEDTRONIC DATA REPORT** button (.

Note: To view, share, download, or delete the Medtronic data report, navigate to the **REPORTS** screen. For more information, refer to "To view, share, download, or delete a report", page 63.

BATTERY LONGEVITY CALCULATOR SCREEN

For the Percept PC neurostimulator, the **BATTERY LONGEVITY CALCULATOR** screen allows you to input patient-specific stimulation and impedance values, within Demo Mode, to estimate the expected neurostimulator battery life for that patient.

Note: Battery longevity cannot be calculated for groups with BrainSense or Adaptive Therapy configured. Monitor the Estimated Battery Life Remaining (Table 10) to determine how stimulation parameters, such as Adaptive Therapy, may affect battery life.

To access the BATTERY LONGEVITY CALCULATOR screen

Quick navigation: (DEMO) HOME > Menu button (> Battery Longevity

Begin on the **HOME** screen in Demo Mode. For information on how to enter Demo Mode, see "DEMO MODE", page 14.

1. Configure all stimulation settings for the program(s) within a group for which you want to calculate battery longevity.

   For information on managing groups and programming, see "MANAGING GROUPS", page 28 and "PROGRAMMING THE INS", page 23.
2. Tap the menu button (in the top-left corner.
3. Tap **Battery Longevity**.
4. Confirm the settings of the active group.
5. Enter the expected average impedance. If using a directional lead, enter the monopolar impedance of a non-segmented electrode.

The app will automatically calculate the estimated battery longevity, displayed at the bottom of the screen.

RECHARGE INTERVAL CALCULATOR SCREEN

For the Percept RC neurostimulator, the **RECHARGE INTERVAL CALCULATOR** screen allows you to estimate the recharge interval (the time period from when the battery is full to when it becomes empty). The estimated recharge interval is based on the stimulation settings for the active group.

Note: Recharge interval estimation cannot be performed in Demo Mode or when the active group has Adaptive Therapy set to Adapting. Monitor the Average Recharge Interval (see "Battery Recharge", page 56) to determine how stimulation parameters, such as Adaptive Therapy, may affect recharge intervals.

To access the RECHARGE INTERVAL CALCULATOR screen

Quick navigation: HOME > Menu button (> Recharge Interval

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. Tap the menu button (in the top-left corner and select **Recharge Interval**.

   Note: You can also access the **RECHARGE INTERVAL CALCULATOR** screen by tapping the Settings button (on the Programming screen and then tapping **Estimate**.
2. Tap **ESTIMATE**.

   The app will calculate the estimated recharge interval, displayed next to the **ESTIMATE** button.

PREFERENCES SCREEN

The **PREFERENCES** screen allows you to set indication-specific initial settings. Settings on the **PREFERENCES** screen will define starting values for all patients programmed using that specific tablet and app. Refer to "Programming settings", page 23 for information on adjusting settings for a session.

To access the PREFERENCES screen

Quick navigation: HOME > Menu button (☰) > Preferences

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (⌂) in the top-right corner.

1. Tap the menu button (☰) in the top-left corner and select **Preferences**.
2. Use the tabs to navigate between indications.
3. Use the controls on the **PREFERENCES** screen to adjust indication-specific initial settings.

   Note: You can reset these settings to their default values by pressing the **RESTORE DEFAULTS** button.

BRAINSENSE SURVEYS SCREEN

About BrainSense Surveys

The **BRAINSENSE SURVEYS** screen has two modes available: Electrode Identifier and Electrode Survey (Table 14). Consider the patient's symptomatic state when measuring LFP.

Table 14. BrainSense Survey modes

Survey mode	Description
Electrode Identifier	BrainSense Electrode Identifier allows you to identify the electrodes on a lead with the greatest and least measured LFP magnitude.
Electrode Survey	Electrode Survey allows you to measure and compare LFP magnitude between electrode pairs on the same lead.

More information about BrainSense Surveys:

- Consider the patient's symptomatic state when measuring LFP.
- Stimulation is turned off for the duration of a BrainSense Survey. Once measurements are completed, the previously active stimulation group is automatically activated.
- You cannot run a session on a hemisphere configured with a pocket adaptor.
- Electrode Identifier is only available for patients who have a dual lead implant.
- If the patient has a directional lead, you can run Electrode Identifier on segments, levels, or both consecutively.
- Electrode Identifier performs a Minimum Separability check to ensure the accuracy of electrode LFP magnitude rankings. The Minimum Separability check determines if the signals are distinct enough to accurately differentiate the electrode location of the signal. If the minimum separability requirement is not met, an "Insufficient Signal Separation" message will be displayed. Refer to "BrainSense Surveys troubleshooting", page 74.
- BrainSense Surveys modes run an artifact check to reveal contacts that contain signal artifacts. When artifacts are detected, the message "Artifact Detected" will be displayed. Refer to "BrainSense Surveys troubleshooting", page 74.
- If the impedance test fails for a configuration, that configuration is unavailable. Refer to "BrainSense Surveys troubleshooting", page 74.

To access the BRAINSENSE SURVEYS screen

Quick navigation: HOME > STIMULATION > OK > Tap active program > BRAINSENSE SURVEYS BUTTON (

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program.
3. Tap the BrainSense Surveys button (.

   Note: After you run an Electrode Identifier session for the first time, tapping the BrainSense Surveys button will display a dropdown list. Select **BrainSense Surveys** from the dropdown list options.

Note: You can also access the **BRAINSENSE SURVEYS** screen from the **HOME** screen by selecting the menu button in the top left corner and then selecting **BrainSense Surveys**.

To run Electrode Identifier

Quick navigation: HOME > STIMULATION > OK > Tap active program > BRAINSENSE SURVEYS BUTTON (> RUN ELECTRODE IDENTIFIER

1. Start on the **BRAINSENSE SURVEYS** screen. Refer to "To access the BRAINSENSE SURVEYS screen", page 68.
2. Select the lead location (right or left hemisphere) using the dropdown list.
3. For directional leads only:
   a. Use the **Levels** tab to view Electrode Identifier results between electrode levels.
   b. Use the **Segments** tab to view Electrode Identifier results between electrode segments.
4. Tap the **RUN ELECTRODE IDENTIFIER** button (.

   Note: The patient should be seated and minimize movements during electrode identification.
5. Follow the on-screen prompts.

   Note: For directional leads only: To generate results on both segments and levels, ensure the on/off toggle is set to on . To resume with the single measurement option selected in step 3, tap the on/off toggle to set it to off. (.
6. Review the signal data for each sense electrode. Electrodes are ranked by signal strength. Refer to section "To view and interpret Electrode Identifier results", page 69.

To run Electrode Survey

Quick navigation: HOME > STIMULATION > OK > Tap active program > BRAINSENSE SURVEYS BUTTON (> RUN ELECTRODE SURVEY

1. Start on the **BRAINSENSE SURVEYS** screen. Refer to "To access the BRAINSENSE SURVEYS screen", page 68.
2. Tap the **Electrode Survey** tab.
3. For directional leads only:
   a. Use the **Levels** tab to view Electrode Survey results between electrode levels.
   b. Use the **Segments** tab to view Electrode Survey results between electrode segments.
4. Tap the **RUN ELECTRODE SURVEY** button (.

   Note: The patient should be seated and minimize movements during the survey.
5. Follow the on-screen prompts.

6. Review the signal data for each sense electrode pair.

   Note: The data shows the magnitude of the LFP signal over a range of frequencies, allowing you to view this data as it is detected across each electrode pair.

To view and interpret Electrode Identifier results

After running Electrode Identifier, the results screen is automatically displayed (Figure 10). From this screen, you can view the measured electrodes organized by the relative magnitude strength of the LFP Signal (most LFP magnitude, medium LFP magnitude, and least LFP magnitude.)

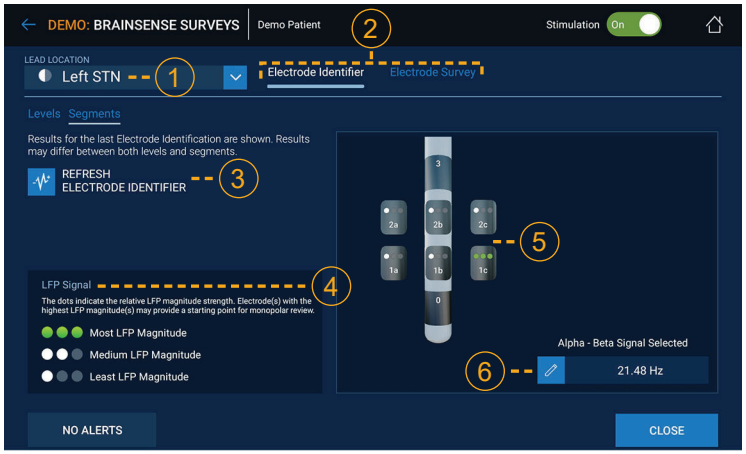

Figure 10. Electrode Identifier results screen (directional lead shown).

①	**Lead location dropdown –** Select a lead location to view or generate new results.
②	**BrainSense Surveys mode tabs –** Toggle between the two BrainSense Surveys modes.

(continued)

③	**Refresh survey button –** Tap this button to generate new Electrode Identifier survey results.
④	**LFP signal legend –** Provides a visual key representing the LFP magnitude ranking for electrodes on the level or segment.
⑤	**Electrode Identifier results –** Review the Electrode Identifier LFP magnitude rankings for each electrode.
⑥	**Adjust frequency pencil –** Tap the Adjust frequency pencil to display the Adjust Frequency pop-up screen. Use this screen to view LFP magnitude results for each electrode across the LFP frequency spectrum. Use the slider to select a new frequency. Tap **UPDATE** to view results for your frequency of interest. **Note:** Vertical lines are displayed on the graphical data to indicate frequencies with insufficient signal separation.

To view Electrode Identifier results from the programming screen

Quick navigation: HOME > STIMULATION > OK > BRAINSENSE SURVEY BUTTON (> VIEW ELECTRODE IDENTIFIER RESULTS

Begin on the **HOME** screen.

Note: To access the **HOME** screen:

- **At start of session:** After opening the app, tap **CONNECT** and follow any on-screen prompts until you reach the **HOME** screen.
- **Mid-session:** Tap the **Home** button (in the top-right corner.

1. On the **HOME** screen, tap **STIMULATION** and proceed to the **GROUPS** screen.
2. Tap an active program
3. Tap the BrainSense Surveys drop down menu button (.
4. Select **View Electrode Identifier Results**. A pop-up screen will display the results from the most recent Electrode Identifier

session. To return to the programming screen, close the window.

USAGE

For information on viewing and interpreting the **Device Usage** tab of the **EVENTS** screen, see "Device Usage", page 56.

TROUBLESHOOTING

This section provides information for noninvasive troubleshooting.

Alerts

The clinician programmer app will display alerts to inform you of specific events or changes in the system.

Read and follow the instructions given in the alert.

There are three levels of alerts in the clinician programmer app:

- **Warning –** Indicates a warning and that the message should be read and acknowledged. Warning level alerts are red.
- **Caution –** Indicates a caution and that the message should be read and acknowledged. Caution level alerts are orange.
- **Notification –** Indicates information.

Alerts can appear in two forms:

- **Pop-up alerts –** messages that appear over the screen. These messages pause the session and require an action before the session can continue.
- **Pending alerts –** messages that appear at the bottom of the screen, but do not pause the session. These messages, when tapped, expand to provide more information.

Communicator and tablet troubleshooting

See Table 15 for a list of potential issues that can occur with the communicator or the tablet, as well as possible solutions for resolving those issues.

Table 15. Communicator troubleshooting

Problem	Possible Solutions
Cannot pair the communicator with the tablet.	When attempting to connect through BLUETOOTH wireless technology: ■ Make sure the communicator is turned on and within range of the clinician tablet. See the 8880T2 Technical Manual for details. ■ Make sure the BLUETOOTH wireless technology is enabled on the clinician tablet.

Table 15. Communicator troubleshooting (continued)

Problem	Possible Solutions
	– Refer to "Communicator icons in tablet status bar", page 17 for what the communicator icons mean when displayed in the tablet status bar.
The communicator cannot communicate wirelessly with the clinician tablet during a programming session.	Possible reasons: ■ You are in an environment where multiple devices are using BLUETOOTH wireless technology and thereby creating interference. ■ You have moved into an environment where the BLUETOOTH wireless technology is prohibited.
	Possible solutions: ■ Use the USB connector cable to connect the communicator to the clinician tablet. ■ Make sure the BLUETOOTH wireless technology is enabled on the clinician tablet. – Refer to "Communicator icons in tablet status bar", page 17 for what the communicator icons mean when displayed in the tablet status bar.
The communicator cannot communicate with the neurostimulator.	■ Metal surfaces can interfere with the communication between the communicator and the neurostimulator. – If the communicator is on a metal table or a metal tray, move the communicator to a non-metal surface. ■ There could be radio-frequency (RF) interference. – Hold the communicator directly over the neurostimulator.
The communicator battery level is low.	■ Open the battery case and replace the batteries. – If needed, refer to the instructions for replacing the communicator batteries in the Model 8880T2 Communicator Technical Manual. ■ After replacing the communicator batteries, the clinician programmer app will connect with the communicator and resume the session.
The clinician tablet, the clinician programmer app, or the	Turn off the power for the clinician tablet or the communicator, then turn the power on.

Table 15. Communicator troubleshooting (continued)

communicator is unresponsive.	
The communicator is damaged	Use a different communicator: ■ Ensure the damaged communicator is turned off before using another communicator. ■ If using a replacement communicator prior to starting a programming session, use the USB connector cable and pair the replacement communicator to the clinician tablet. – Refer to "Pairing the communicator with the clinician tablet", page 18. Or – If replacing the communicator while in a programming session, use the USB connector cable to connect the communicator to the clinician tablet and continue with the programming session.

Stimulation Settings Out Of Range (OOR) troubleshooting

A Stimulation Settings Out Of Range (OOR) alert appears when the neurostimulator battery is unable to produce the levels of energy required for the current stimulation settings.

This section outlines advanced troubleshooting steps for resolving Out Of Range alerts. For basic troubleshooting steps, refer to "STIMULATION SETTINGS OUT OF RANGE (OOR)", page 22.

If an OOR message appears during a programming session, try the following to remain in range:

1. Consider measuring impedance to see if there is an open or short circuit in the system.
2. Change the electrodes that are providing stimulation.

BrainSense troubleshooting

Table 16 lists possible problems while setting up or managing BrainSense.

Table 16. BrainSense troubleshooting

Problem	Possible Solutions
All electrode configurations have the **Artifact Detected** message.	Ensure that patient movement is minimized, then tap **REFRESH SIGNAL TEST** ( ). **Note:** Using an electrode configuration with an artifact detected may interfere with your ability to capture meaningful BrainSense information, and it may impact Adaptive Therapy performance.
No signal is detected.	Consider the patient's underlying neurological condition and current treatment status as they may impact the LFP signal. If there is no signal detected, there could be several underlying reasons: 1. The sensing electrodes may not be in the necessary anatomical space. 2. Check the lead for damage. See "ELECTRODE IMPEDANCE TROUBLESHOOTING (POST-IMPLANT)", page 61. 3. In some cases, unique patient physiology may affect the results of a signal test. 4. Some patients may not have a measurable LFP signal. 5. The signal may be less than 1.2 µVp which is below the system minimum for auto-detection. Retry the signal test at a later time, when factors that affect the LFP signal may have changed.
Artifact Detected or no signal is detected >1.2 µVp	Consider performing amplitude titration while using BrainSense streaming to identify an LFP signal of interest that is responsive to stimulation. Refer to "To use LFP streaming data to view real-time effects of stimulation", page 45 for details on performing amplitude titration.
Electrode configuration is unavailable due to impedance	1. Check the lead for damage. See "ELECTRODE IMPEDANCE TROUBLESHOOTING (POST-IMPLANT)", page 61. 2. Select an alternative available electrode configuration for BrainSense.
LFP does not appear to change over time on **Timeline** screen)	1. If LFP thresholds are too far apart, smaller changes in LFP may not be readily visible. Consider narrowing the range between the LFP thresholds.

Table 16. BrainSense troubleshooting (continued)

	a. Navigate to the **BrainSense** tab of the Programming screen. See "To stream BrainSense data", page 45. b. Manually adjust the LFP threshold(s) by sliding the adjustment flag(s) (on the graph to increase or decrease the corresponding LFP threshold(s). 2. Use streaming data to confirm that the new LFP thresholds are achieving the desired effect. See "To stream BrainSense data", page 45. If these steps do not resolve the issue, the signal used may no longer be viable. Refer to “No signal is detected” earlier in this table.
No thresholds shown on **Timeline** screen)	Thresholds are only shown on the **Timeline** screen for times the patient spent in a group with BrainSense configured and with thresholds captured. Check that thresholds were captured as part of the **BrainSense Setup** workflow. See "To set up or adjust BrainSense", page 36.
RECAPTURE THRESHOLDS alert appears	This alert appears when the LFP signal is minimally responsive to changes in stimulation amplitude, which may impact Adaptive Therapy performance. 1. Recapture the thresholds using different stimulation values, if needed. 2. If the issue persists, try increasing the Sensing Blanking Duration through the **ADVANCED SETTINGS** menu (available on the **BrainSense setup** screen). **Note:** If the stimulation level is above 5 mA amplitude) or 120 µs (pulse width), the artifact of stimulation may cause the LFP to appear elevated when capturing the Lower LFP Threshold. 3. If the issue persists, assess other electrode configurations for an LFP signal that does not trigger the **RECAPTURE THRESHOLDS** alert. 4. Consider using BrainSense streaming with amplitude titration. Refer to "To use LFP streaming data to view real-time effects of stimulation", page 45.

Table 16. BrainSense troubleshooting (continued)

Problem	Possible Solutions
	If no electrode configurations result in successfully captured thresholds, then Adaptive Therapy may not be optimal for the patient.
Adaptive Therapy is chronically delivering stimulation that is too low to achieve the desired therapeutic effect.	Consider the following actions: 1. Navigate to the **Timeline** screen. See "Timeline", page 55 for more information. 2. If the **Timeline** screen shows that stimulation stays at the upper limit for extended periods of time, **increase** the **maximum amplitude limit**, if tolerated by the patient and without causing intolerable side effects. 3. If the **Timeline** screen does not show stimulation as “stuck” at the upper limit, try the following: a. Navigate to the **BrainSense** tab of the Programming screen. See "To stream BrainSense data", page 45. b. **Decrease** the **upper LFP threshold**. This will help the system adapt up to the maximum amplitude limit more frequently and increase therapeutic output. c. If the issue persists, **decrease** the **lower LFP threshold**. This will help to decrease the amount of time the stimulation ramps down. d. If the issue persists, navigate to the Programming screen, then **increase** the **minimum amplitude limit**. See "To program", page 24 for more information.
Adaptive Therapy is transiently delivering stimulation that is too low to achieve the desired therapeutic effect.	Consider the following actions: 1. Navigate to the **Summary** tab of the **BrainSense** workflow. See "To set up or adjust BrainSense", page 36 for more information. 2. Lengthen the Transition Down Duration. See "About Transition Durations", page 42. 3. Shorten the Transition Up Duration, ensuring that it does not cause the patient discomfort. 4. Tap the **ADVANCED SETTINGS** button (on the **Summary** screen. Then, decrease the Upper Onset Duration and increase the Lower Onset Duration. 5. If the issue persists, navigate to the Programming screen, then **increase** the **minimum amplitude limit**. See "To program", page 24 for more information.

Table 16. BrainSense troubleshooting (continued)

	6. If the issue persists, consider decreasing the Detection Blanking Duration.
Adaptive Therapy is chronically delivering stimulation that is higher than necessary to achieve the desired therapeutic effect	Consider the following actions: 1. Navigate to the **Timeline** screen. See "Timeline", page 55 for more information. 2. If **Timeline** screen shows stimulation as “stuck” at the lower limit, **decrease** the **minimum amplitude limit**. 3. If Timeline screen does not show stimulation as “stuck” at the lower limit, try the following: a. Navigate to the **BrainSense** tab of the Programming screen. See "To stream BrainSense data", page 45. b. **Increase** the **lower LFP threshold**. This will help the system adapt down to the minimum amplitude limit more frequently. c. If the issue persists, **increase** the **upper LFP threshold**. This will help decrease the amount of time the stimulation ramps up. d. If the issue persists, navigate to the Programming screen, then **decrease** the **maximum amplitude limit**. See "To program", page 24 for more information.
Adaptive Therapy is transiently delivering stimulation that is higher than necessary to achieve the desired therapeutic effect	Consider the following actions: 1. Navigate to the **Summary** tab of the **BrainSense** workflow. See "To set up or adjust Adaptive Therapy", page 41 for more information. 2. Lengthen the Transition Up Duration. See "About Transition Durations", page 42. 3. Shorten the Transition Down Duration, ensuring that it does not cause the patient discomfort. 4. Tap the **ADVANCED SETTINGS** button (, then increase the Upper Onset Duration and decrease the Lower Onset Duration. 5. If the issue persists, navigate to the Programming screen, then **decrease** the **maximum amplitude limit.** Refer to "To program", page 24.
While streaming in Single Threshold Mode, Adaptive Therapy repeatedly	Consider the following actions:

Table 16. BrainSense troubleshooting (continued)

Problem	Possible Solutions
ramps to the upper stimulation limit immediately after stimulation adjusts to the lower limit.	1. Navigate to the Summary tab of the BrainSense workflow. See "To set up or adjust Adaptive Therapy", page 41 for more information. 2. Tap the ADVANCED SETTINGS button (, then increase the Detection Blanking Duration. 3. If the issue persists, then continue to increase Detection Blanking Duration until the issue is resolved.
Adaptive Therapy transiently delivers stimulation at the upper limit immediately after Resuming or activating Adaptive Therapy.	Consider the following actions: 1. Navigate to the Summary tab of the BrainSense workflow. See "To set up or adjust Adaptive Therapy", page 41 for more information. 2. Tap the ADVANCED SETTINGS button (, then increase the Adaptive Startup Delay. 3. If the issue persists, then continue to increase the Adaptive Startup Delay until the issue is resolved.

BrainSense Surveys troubleshooting

Table 17 lists possible problems you may encounter while setting up or managing Electrode Identifier or Electrode Survey.

Table 17. BrainSense Surveys troubleshooting

Problem	Possible Solution(s)
Note: For **Electrode Identifier** troubleshooting only Minimum separability check failed at the peak detected. Error message displayed: **Insufficient Signal Separation**	1. Tap **REFRESH ELECTRODE IDENTIFIER** to generate new results. 2. Use the Adjust Frequency screen to select another peak where minimum separability requirements are met.
Note: For **Electrode Identifier** troubleshooting only	Tap **REFRESH ELECTRODE IDENTIFIER** to generate new results.

Table 17. BrainSense Surveys troubleshooting (continued)

Problem	Possible Solution(s)
Minimum separability check failed across all signals. Error message displayed: **Insufficient Signal Separation** **No Signal Selected**	
Impedance Issue detected on all signals	Consider the following actions: 1. Assess options to reduce impedance. For more information on impedance troubleshooting, refer to "ELECTRODE IMPEDANCE TROUBLESHOOTING POST-IMPLANT)", page 61. 2. Tap the **REFRESH** button (to generate new results.
Artifact Detected	Ensure patient movement is minimized, then tap the **REFRESH** button (. **Note:** Viewing Electrode Identifier results for contacts that contain signal artifacts may interfere with your ability to deduce clinically meaningful information from the data.

Using impedance measurements for troubleshooting

Refer to "ELECTRODE IMPEDANCE TROUBLESHOOTING INTRAOPERATIVE)", page 60 for information on intraoperative troubleshooting.

Refer to "ELECTRODE IMPEDANCE TROUBLESHOOTING POST-IMPLANT)", page 61 for information on post-implant troubleshooting.

Resetting a neurostimulator

To reset a neurostimulator using the clinician programmer app

If a neurostimulator persistently cannot be found and communication to the neurostimulator has been lost, use the following steps to reset the neurostimulator using the clinician programmer app.

1. Open the application.
2. Tap the Settings button (in the top-right corner of the **CONNECT** screen, then tap **About**.
3. Tap the **Device** tab.
4. After reading the on-screen text, tap the **Reset Neurostimulators** button, then confirm the action.

After sending the reset command, the communicator will beep.

Contact the appropriate Medtronic representative listed on the back cover of this manual if additional assistance is needed.

To reset a Percept RC neurostimulator using the Model WR9230 recharger

If the clinician programmer app or recharger is unable to communicate with the Percept RC neurostimulator, perform the following steps to reset the neurostimulator using the recharger. Contact the appropriate Medtronic representative listed on the back cover of this manual if additional assistance is needed.

Note: If the volume on the recharger is turned off, you will be unable to hear the audio feedback in the following steps. See the manual that came with the recharger for instructions to change the recharger volume.

1. Connect the charging dock to a power supply. Place the recharger on the dock as if to charge the recharger.
2. Palpate the patient's skin to determine the approximate location of the neurostimulator.
3. With the recharger on the dock, enter Physician Recharge Mode by using the button press sequence: short, short, long. You will

see the battery indicator fill up and hear a beep with each button press.

Note: A short button press is 1-2 seconds. A long button press is 4-6 seconds.

4. The light on the power button indicator will show a spinning amber light and the recharger will beep.
5. Pick up the recharger from the dock and hold it over the patient's implanted neurostimulator. Within 2 minutes, the power button indicator will show a flashing amber light and beeping will get faster. This means the recharger is preparing to reset the neurostimulator.
6. Keep the recharger over the implanted neurostimulator after the beeping stops. The reset will start after the beeping ends and will take up to 1 minute to complete. The power button indicator light will change to a slow pulse when the reset has completed.
7. After the reset, the recharger transitions to a special recharging session that may take up to 30 minutes if the neurostimulator battery needs to be recovered. Keep the recharger over the implanted neurostimulator until it enters a normal recharging session.

   Note: The recharger indicator light will turn green when the implanted neurostimulator enters a normal recharging session.
8. After resetting and recharging the neurostimulator using Physician Recharge Mode, check therapy status with the clinician programmer app and turn therapy on if necessary.

Patient control device error codes

Patient control devices display text and iconic error and informational messages. Some messages provide an error code and tell the patients to contact their physician. Common error codes and their troubleshooting procedures are displayed in Table 18. Contact the appropriate Medtronic representative listed on the back cover of this manual if additional assistance is needed.

Table 18. Contact Physician error codes on patient control devices

Error code	Explanation
1703 2703 OOR	An Out Of Range (OOR) situation has occurred. The neurostimulator cannot deliver amplitude at the programmed value. The patient must come into the clinic, and the clinician programmer must be used to determine how to increase the delivered amplitude.
570 580 606	Contact Medtronic.
1714 2714	No programs or groups were saved by the clinician programmer. The neurostimulator must be reprogrammed.
1035 1709 EOS	The neurostimulator has reached end of service EOS) and therapy is not available. Replace the neurostimulator.
1710 ERI	The non-rechargeable neurostimulator is within 10 weeks of its scheduled end of service. Please schedule a date to replace the neurostimulator.
1704 1712 1713 1717 2712 2713 2717	The patient must come into the clinic. If using an older patient control device, retry using a newer patient control device. If the issue persists, contact Medtronic.
810 1708 1714 2708 2714	The patient must come into the clinic, and the clinician programmer must be used to determine neurostimulator status. Settings may need to be re-configured. Review neurostimulator settings with the patient control device to confirm restored function. If the issue persists, contact Medtronic.
2718	Stimulation turned off unexpectedly. The patient may be able to turn stimulation back on using their patient control device without coming into the clinic.

Table 18. Contact Physician error codes on patient control devices (continued)

Error code	Explanation
	If the issue persists, the patient must come into the clinic. Use the clinician programmer to reduce stimulation and then try turning therapy on.

Patient unable to connect a neurostimulator

If the patient persistently encounters the **Not Found** screen or the **No Device Response** screen and is unable to connect to his or her communicator, it may be because the handset was paired to the wrong communicator during the pairing process.

In these instances, the patient's handset must be used to remove the pairing to the wrong communicator before the handset can pair to the patient's communicator.

To remove a paired communicator

After opening the patient application on the handset, the first screen to appear is the **CONNECT** screen.

1. Tap the Settings button (in the top-right corner of the **CONNECT** screen.
2. Tap the right arrow button (to navigate to information about the communicator.
3. Tap the **REMOVE COMMUNICATOR** button.
4. Tap the **REMOVE** button on the alert screen that appears.

Now the handset is unpaired from all communicators and can be paired to the desired communicator.

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Medtronic

Medtronic Deep Brain Stimulation Therapy

Implanted neurostimulators

Information for prescribers

! USA Rx only

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Information available for the Deep Brain Stimulation Therapies:

The information for prescribers manual provides information about contraindications, warnings, precautions, adverse events, sterilization, and component disposal. The information for prescribers addendums contain indication-specific information. For customers in Japan, the appropriate package insert provides information about safety, contraindications, warnings, precautions, and adverse events.

The indications sheet provides information about indications and related information. For customers in Japan, the appropriate package insert provides information about indications.

The system eligibility and battery longevity manual describes programming considerations and provides battery longevity information to aid in the appropriate neurostimulator selection.

MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neurostimulation system.

Product manuals, such as programming guides, recharging guides, and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.

! USA **The clinical summary provides information about the clinical study results for the neurostimulation system.**

Contraindications

Implantation of a deep brain stimulation (DBS) system is contraindicated for these situations:

Diathermy - Patients exposed to diathermy. Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy can also damage the neurostimulation system components, resulting in loss of therapy and requiring additional surgery for system explantation and replacement. Advise your patient to inform all their health care professionals that they should not be exposed to diathermy treatment.

Injury to the patient or damage to the device can occur during diathermy treatment when:

- the neurostimulation system is turned on or off.
- diathermy is used anywhere on the body—not just at the location of the neurostimulation system.
- diathermy delivers heat or no heat.
- any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body.

Certain magnetic resonance imaging (MRI) procedures - Use of a full body transmit radio frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area is contraindicated for patients with the following implanted DBS systems or system components:

- Activa SC Model 37602 Neurostimulator
- Model 64001 and Model 64002 pocket adaptors implanted with any DBS system

Tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death, can occur if a contraindicated MRI scan is performed on a patient with any of these DBS systems.

Refer to the MRI guidelines for Medtronic deep brain stimulation systems Instructions for use manual associated with this product for comprehensive safety information and instructions.

Unable to operate patient devices - Patients who are unable, or do not have the necessary assistance, to properly operate the patient control device (eg, patient programmer, therapy access controller) or a charging system (applicable to rechargeable DBS Systems only).

Transcranial magnetic stimulation (TMS) - Contraindicated for use in patients with an implanted DBS System.

Warnings

Avoid excessive stimulation - There is a potential risk of brain tissue damage from high amplitude and wide pulse width parameter settings.

Programming at high amplitudes and wide pulse widths should only be done with due consideration of the charge density warning described in the software application programming guide.

The Medtronic DBS System can be programmed to use parameter settings outside the range of those used in the clinical studies. If the programming of stimulation parameters exceeds charge density limits, the clinician programmer will display a charge density warning.

Note: Higher amplitudes and wider pulse widths may indicate a system problem or a less than optimal lead placement.

Case damage - If the neurostimulator case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

Coagulopathies - Use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Consider underlying factors, such as previous neurological injury, or prescribed medications (anticoagulants) that may predispose a patient to the risk of bleeding.

Electromagnetic interference (EMI) - 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. Neurostimulators include features that provide protection from EMI. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, sources of strong EMI can result in the following effects:

- **Serious patient injury or death**—it is possible for the extension, lead, or both to “pick up” EMI and deliver an excess current causing tissue damage, including brain tissue damage.
- **System damage**—resulting in a loss of or change in symptom control and requiring surgical replacement.
- **Operational changes to the neurostimulator**—causing it to turn on or off, or to reset to power-on-reset POR) settings, resulting in loss of stimulation, return of symptoms, and in the case of a POR, may require reprogramming by a clinician.
- **Unexpected changes in stimulation**—causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as jolting or shocking.

Refer to "Appendix A: Electromagnetic interference (EMI) and mechanical interference" on page 20 for guidelines on medical procedures that generate EMI and the possible adverse effects of EMI on an implanted DBS system.

MR Conditional - Medtronic DBS Therapy systems have been found to be MR Conditional. Refer to safety information and instructions in the **MRI guidelines for Medtronic deep brain stimulation systems Instructions for use** manual. Do not conduct an MRI examination on a patient with any implanted DBS system component until you read and fully understand all MRI information in this manual and the safety

information and instructions in the **MRI guidelines for Medtronic deep brain stimulation systems Instructions for use** manual. Scanning under different conditions may result in severe patient injury or device malfunction.

Explantation and MRI considerations - To ensure MRI eligibility for patients with partially-explanted DBS systems that no longer provide therapy, the extension must be disconnected from the lead and the neurostimulator and removed. If the lead is not removed, it must be capped. Failure to disconnect and remove the extension may result in heating at the lead electrodes, which can cause thermal lesions. These lesions may result in coma, paralysis, or death. Failure to cap the lead may result in unintended stimulation.

Placement of lead-extension connector in neck - Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture, which would require surgical replacement.

Psychotherapeutic procedures - Safety has not been established for psychotherapeutic procedures using equipment that generates EMI for example, electroconvulsive therapy in patients who have an implanted DBS System.

Single use - Do not reuse, reprocess, or resterilize single use products. Reusing, reprocessing, or resterilizing may compromise the functional integrity of the products and may create a risk of contamination, which could result in patient injury, illness, or death.

Theft detectors and screening devices - Theft detectors found in retail stores, public libraries, etc, and airport/security screening devices may cause the stimulation power source of an implantable neurostimulation system to switch off. It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. For other indications, higher levels of stimulation have been described as uncomfortable "jolting" or "shocking") by some patients as they pass through these devices.

Refer to "Appendix A: Electromagnetic interference (EMI) and mechanical interference" on page 20 for more information.

Use as indicated and instructed - Only use compatible products for the indicated therapy and indicated populations. Failure to use compatible products per labeling indications and instructions may result in product damage, patient injury, or death.

System implant

Compatibility, all components - Follow these guidelines when selecting system components for either initial implant or replacement:

- **Medtronic components:** Use only Medtronic Neuromodulation components that are compatible or specified in an intended use statement (if present). For each product, refer to the applicable indication insert and package label for this information.

  Components are compatible when the following conditions are met:
  - Components have the same indication.
  - For implanted components, the contact spacing and the number of electrode contacts at the connections for the lead and extension/neurostimulator or extension and neurostimulator are the same.

  - SenSight components are compatible only with other SenSight components, unless specifically stated in a SenSight product manual.
- **Non Medtronic components:** No claims of safety or efficacy are made with regard to the compatibility of using non Medtronic components with Medtronic components. Refer to the non Medtronic documentation for information.

Interaction with implanted cardiac devices - When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), clinicians involved with both devices eg, neurologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery.

Possible effects of implanted device interaction include these hazards:

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation system may interact with the sensing operation from a cardiac device and could result in an inappropriate response of the cardiac device.

To minimize possible interactions, take these steps:

- Implant the devices as far away as possible from each other, and comply with any additional instructions.
- Program the neurostimulator to a bipolar configuration and to a minimum rate of 60 Hz, and program the cardiac device to bipolar sensing.

See also: "Neurostimulator implant location" and "Neurostimulator location".

Abandoned systems and EMI considerations - If any DBS System components (neurostimulator, lead, extension, or a fragment of a lead or extension) remain implanted in the patient's body after a partial system explant, the patient is still susceptible to possible adverse effects from EMI. These effects include induced current and component heating, which may result in shocking or jolting the patient and tissue damage resulting in serious injury or death. Advise patients who have any DBS System components implanted in their body to notify all medical personnel that they have an implanted DBS System.

Extension replacement and MRI considerations - Evaluate MRI scan eligibility when selecting system components for replacement. To facilitate full-body MRI scan eligibility, consider replacing a two-pronged quadripolar extension with an in-line extension instead of implanting a pocket adaptor during neurostimulator revision surgery. MRI using a full body transmit radio-frequency RF coil, a receive-only head coil, or a head transmit coil that extends over the chest area is contraindicated for patients implanted with a pocket adaptor.

Component failures - The DBS System may unexpectedly cease to function due to certain events. These events, which can include electrical short or open circuits, conductor wire fracture, and insulation breaches, cannot be predicted. The patient's disease symptoms will return if the device ceases to function.

Component packaging - Visually inspect the sterile packaging for damage that may invalidate device sterility before opening, and inspect the components before use. Do not use a component if the following circumstances have occurred:

- The storage package has been pierced or altered and component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage and the component may not function properly.
- The use-by date has expired and component sterility cannot be guaranteed and infection may occur; also, neurostimulator battery longevity may be reduced and may require early replacement.

Component handling - Handle the implantable components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments, which may result in intermittent or loss of stimulation, requiring surgical replacement. Refer to the appropriate implant manual for additional instructions.

Extension routing for multiple leads - When multiple leads are implanted, route the lead-extensions so the area between them is minimized (Figure 1). If the lead-extensions are routed in a loop, the loop will increase the potential for electromagnetic interference (EMI).

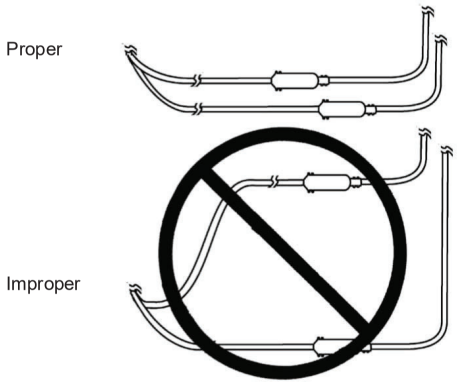

Figure 1. *Routing for multiple lead-extensions.*

Neurostimulator implant location - Implant the device as far away as possible from another active implanted device (for example, pacemaker, defibrillator) to minimize possible interaction between the devices. For information on interactions between multiple devices, consult the manufacturer s labeling for risks associated with the other devices.

Device specific considerations - Rechargeable Neurostimulators

Patient selection (for rechargeable neurostimulators only)

Consult with the neurologist who will provide follow-up care before selecting a rechargeable neurostimulator.

It is critical that the patient checks the rechargeable battery status regularly. Medtronic recommends a practice period for the patient and associated caregiver before implant, to assess whether the patient will be willing and able to incorporate the required recharging activities into current activities of daily living.

Selection of patients living in assisted care or nursing home facilities is not recommended, because maintaining therapy may be relegated to the care staff who may not be adequately trained to assist with recharge activities.

Careful consideration should be given to determining if a patient is appropriate for a rechargeable neurostimulator. Consider these patient abilities for the expected duration of the implant period:

- Patient's ability to use the patient control device and correctly interpret the icons that appear on the screen.
- Patient's ability to regularly monitor the status of the rechargeable battery and respond appropriately.
- Patient's ability to accurately locate their implanted neurostimulator, properly position the recharging system for sufficient coupling, and monitor progress during the recharging session.
- Patient's ability to perform charging activities for sufficient duration and frequency to maintain therapy and to perform charging activities on an ongoing basis.

Special consideration should be given to these aspects of the patient's care:

- Available level of support from a caregiver, to assist the patient with monitoring and recharging activities.
- Expected effect from cessation of therapy, should the patient fail to recharge on schedule or when alerted.
- Patient's age, as very young or very old patients may have difficulty performing required monitoring and recharging of the device.
- Patient's mental capacity, as patients with cognitive impairment or those prone to developing dementia would likely have difficulty performing device-related tasks without assistance.
- Patient's physical ability, as patients with higher degrees of motor impairment might have difficulty with the physical requirements of monitoring and recharging the device.
- Patient's visual ability, as patients need to be able to read the screen display on the patient device to assess battery status.
- Patient's willingness to use the patient control device alert or a different method that will be effective in reminding the patient to check the battery status on a regular basis.

- Patient's (and caregiver's) willingness to continue recharging activities as necessary under all circumstances, for example, power outages, travel, and hospitalizations, and recognize the critical nature of maintaining a charged battery in the neurostimulator.

Importance of regular recharging (rechargeable neurostimulator only) - Inform patients and their caregivers that it is important to maintain a regular schedule of recharging.

Charging system (rechargeable neurostimulator only)

Wound contact - Do not use the recharger on an unhealed wound. The recharging system is not sterile, and contact with the wound may cause an infection.

Low battery charge level - Advise patients to charge the neurostimulator on a regular basis to prevent the battery from becoming discharged. How often the neurostimulator battery needs to be charged depends on the therapeutic parameter settings and battery usage for each individual patient.

- A low battery charge is indicated by the **Low battery** screen display on the patient device.
- A discharged battery is indicated by the **Low battery** screen and no available therapy.

Activa RC Model 37612 only

If the battery is not recharged and allowed to remain in a discharged state, the neurostimulator will become overdischarged.

The patient cannot charge an overdischarged neurostimulator. However, the clinician may be able to restore the battery function using the Physician Recharge Mode on the recharger. Refer to the troubleshooting section of the applicable clinician programmer application manual.

Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways:

- Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced.
- Battery function is not restored and the neurostimulator must be surgically replaced. Battery function is not restored when:
  - The neurostimulator battery is permanently damaged.
  - The neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

Clinician programming

Effects on other medical devices - The DBS System may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient's benefit from each device.

Programmer interaction with other active implanted devices - When a patient has a neurostimulator and another active implanted device (eg, pacemaker, defibrillator, neurostimulator), the radio frequency (RF) signal used to program these devices may reset or reprogram the other device. To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital and after each programming session of either device (or as soon as possible after these times).

Also, inform patients to contact their clinician immediately if they experience symptoms that could be related to either device or to the medical condition treated by either device.

Patient information

Programming and patient control devices

Patient control devices may affect other implanted devices - Do not place the patient control device over another type of active implanted medical device eg, pacemaker, defibrillator, another type of neurostimulator). The patient control device could unintentionally change the operation of the other device.

Patient activities

Activities requiring excessive twisting or stretching - Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation system. Activities that include sudden, excessive or repetitive bending, twisting, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component.

Component manipulation by patient - Advise your patient to avoid manipulating the implanted system components (for example, the neurostimulator, the burr hole site . This manipulation can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site. **Note:** Manipulation may cause device inversion, making an Activa RC Model 37612 rechargeable neurostimulator difficult to charge.

Patient activities and environmental warnings - Patients should exercise reasonable caution in avoidance of devices that generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to switch on or off. The system also may unexpectedly cease to function. For these reasons, the patient should be advised about any activities that would be potentially unsafe if their symptoms unexpectedly return. For additional information about devices that generate EMI, call Medtronic. Refer to the contacts listed at the end of this manual.

Scuba diving or hyperbaric chambers - Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician.

Skydiving, skiing, or hiking in the mountains - High altitudes should not affect the neurostimulator, however, the patient should consider the movements involved in any planned activity and avoid putting undue stress on the implanted system. Patients should be aware that during skydiving, the sudden jerking that occurs when the parachute opens

may cause lead dislodgement or fractures, which may require surgery to repair or replace the lead.

Precautions

Clinician training

Please see the appropriate IFP addendum for more information on indication-specific clinician training.

Implanting clinicians - Implanting clinicians should be experienced in DBS procedures and should review the procedures described in the implant manuals before surgery.

Prescribing clinicians - Prescribing clinicians should be experienced in the diagnosis and treatment of DBS-indicated diseases and should be familiar with the use of the neurostimulation system.

Medical procedure coordination

Turning the neurostimulator off - The decision to turn off a patient's implanted neurostimulator in order to perform medical diagnostic or therapeutic procedures may result in unforeseen consequences and should therefore be carefully considered based on the patient's underlying medical condition. Consultation with the appropriate medical professionals prescribing or implanting clinicians) is recommended.

Storage and sterilization

Sterilization - Medtronic has sterilized the package contents according to the process indicated on the package label before shipment. This device is for single use only and is not intended to be resterilized.

Storage and operating temperature - Some products may be damaged if stored or operated outside the temperature range specified for the product. For products with limited storage and operating temperature ranges, see the applicable product manuals and package labels.

System implant

Multiple implants - The long-term safety associated with implanting more than one lead on the same side of the brain is unknown.

Neurostimulator location - Select a location that meets the following criteria:

- A minimum of 20 cm (8 in) away from another Medtronic neurostimulator to minimize telemetry interference and possible inappropriate therapy
- Away from bony structures to minimize discomfort at the neurostimulator site
- Away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort
- Accessible to the patient for proper operation of a patient control device and for proper neurostimulator recharging (rechargeable neurostimulator only

Any of these hazards may require a surgical revision or replacement.

Clinician programming

Parameter adjustment - To prevent possible unpleasant stimulation, decrease the amplitudes to 0.0 V or 0.0 mA before taking the following steps:

- Connecting or disconnecting the cable to the screener or external neurostimulator
- Replacing the external neurostimulator or screener batteries

Programmer interaction with a cochlear implant - When the patient has a cochlear implant, minimize or eliminate the potential for unintended audible clicks during telemetry by keeping the external portion of the cochlear system as far from the programming components as possible, or by turning off the cochlear implant during programming.

Programmer interaction with flammable atmospheres - The programmer is not certified for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

Screening with external neurostimulators - When screening a patient who has multiple leads implanted, do not operate multiple external neurostimulators simultaneously. The signals from simultaneously operated external neurostimulators can interfere with each other and result in incorrect results.

Clinician information and general guidance for patients

Before surgery, the patient and family should be advised of the known risks of the surgical procedure and the therapy, as well as the potential benefits. After the DBS system is implanted, the patient should also be advised to read the patient manual included in the neurostimulator package.

Clinicians should provide patients with information about the neurostimulation system:

- Components of the neurostimulation system: lead, extension, and neurostimulator
- Instructions for using the neurostimulation system, including the patient control device and charging system rechargeable neurostimulators only)
- Indications, contraindications, warnings, and precautions for a neurostimulation system

Clinicians should also instruct patients how to manage their therapy:

- Always inform any health care personnel that they have an implanted neurostimulation system before any procedure is begun.
- Contact their clinician if they notice any unusual symptoms or signs.

For applicable geographies, an International Implant Card, which contains identifying information about the implanted device, is included in each device package. After device implant, complete each card with the patient's name, the implant date, and the healthcare center's name and address. Give all cards to the patient.

Patient information

Programming and patient control devices

Group selection - Patients should select the group recommended by the clinician for the desired therapeutic effect. Use of another group may result in unpleasant stimulation when stimulation is turned on.

Patient device use - When operating a patient control device or charging system (rechargeable models only), use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the device could occur. The consequences of using a battery-powered device near flammable or explosive atmospheres are unknown.

Recharger use - Check for skin irritation or redness near the neurostimulator during recharging. Do not sit or lie on, or apply excessive pressure to the components of the recharging system. Take periodic breaks during prolonged recharging. Although no direct cause and effect has been established, some patients have reported heating sensation, discomfort, blistering not caused by heating, skin irritation, or redness near the implanted neurostimulator during or after recharging. Contributing factors may include excessive pressure on the components of the recharging system, prolonged recharging periods, or individual patient physiological factors.

Patient activities

Activities requiring coordination - Loss of coordination is a potential side effect of DBS Therapy. Patients should exercise reasonable caution when participating in activities requiring coordination, including those that they were able to perform prior to receiving DBS Therapy eg, swimming).

Bathing - Patients should exercise reasonable caution when bathing.

Hospital or medical environment

Before undergoing any medical procedure, patients should always inform any health care personnel that they have an implanted neurostimulation system. There is potential for an interaction between the neurostimulation system and equipment used for the procedure—even when both are working properly.

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, because of higher energy levels, sources such as transmitting antennas found on various diagnostic and therapeutic equipment may interfere with the DBS System.

See "Appendix A: Electromagnetic interference (EMI) and mechanical interference" on page 20 for more information on electromagnetic interference.

In order to minimize the effects of EMI for some medical procedures, it is recommended to turn off the neurostimulator during the procedure. The clinician ordering the procedure should contact the implanting clinician or prescribing clinician to determine if it is appropriate to turn off the neurostimulator based on the patient's underlying medical condition.

Implanting or prescribing clinicians should also explain the following to their patients:

- Whether or not it is safe to have their neurostimulator turned off
- What effects patients may experience when their neurostimulator is turned off and turned back on again
- Whether or not patients should contact them before turning their neurostimulator off

Effect on electrocardiograms (ECGs) - Ensure the neurostimulator is turned off prior to initiating an ECG. If the neurostimulator is on during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

Home or occupational environment - Medtronic DBS neurostimulators should not be affected by normal operation of electrical equipment such as household appliances, electric machine shop tools, microwave ovens, RF transmitting systems, or microwave frequency transmitting systems. A strong magnetic field electromagnet or permanent magnet) can switch the neurostimulator output from on to off or off to on, but does not change the programmed parameters.

Advise your patients to avoid or to exercise care when approaching the following:

- Theft detectors
- Airport/security screening devices
- Large stereo speakers with magnets
- Electric arc welding equipment
- Electric steel furnaces
- Electric induction heaters (used in industry to bend plastic)
- Power lines
- Electric substations and power generators

If your patient suspects an electrical device or magnet is interfering with the neurostimulator, advise him/her to move away from it, or turn the device off. Then, the patient can use the patient control device to set the neurostimulator back to the desired on or off state. When switched on, the neurostimulator will resume stimulation at the previously programmed level.

Radio-frequency sources - Analog and digital cellular phones, AM/FM radios, cordless phones, and conventional wired telephones may contain permanent magnets. To prevent undesired turning on or off of the stimulation, these devices should be kept at least 10 cm (4 in) away from the implanted neurostimulator.

Intended target population

The target population is patients who have conditions consistent with the DBS indications. See associated indications sheet for more information.

Use during pregnancy - The safety and effectiveness of DBS therapy have not been established for pregnancy.

Adverse events

The following adverse events may occur with DBS therapy. Specific adverse events or groups of adverse events may be more relevant depending on the patient indication and site of stimulation. For additional indication-specific adverse events, see the appropriate indication-specific IFP addendum.

Risks (potential adverse events) related to the lead, extension, or neurostimulator implant, explant, or revision procedures:

- Immediate intracranial hemorrhage or cerebral infarction which could be symptomatic, or which could result in temporary or permanent neurological injury or death
- Asymptomatic intracerebral hemorrhage or ischemia related to the DBS lead implant identified through postoperative imaging
- Complications related to anesthesia, including allergic reaction, hypotension, nausea and vomiting, headache, and other symptoms
- Complications or effects related to the device implantation or removal procedure, including lead insertion or removal difficulty, failure of the burr hole ring and cap, mechanical or electrical complications of the device, lead(s) not within target requiring replacement
- Complications or effects related to the tunneling procedure, including injury to nerve tissue (such as the spinal accessory nerve), vascular injury that may result in prolonged hospitalization, and tunneling through unintended anatomy such as in between the ribs and entering the thoracic cavity)
- Cerebrospinal fluid leakage also called CSF fistula
- Pneumocephalus
- New onset seizures associated with the lead implant procedure
- General medical complications such as deep vein thrombosis, postoperative fever, and general postoperative discomfort

Risks (potential adverse events) after implantation of the lead s), extension(s, or neurostimulator(s):

- Delayed intracranial hemorrhage or cerebral infarction which could be symptomatic, or which could result in temporary or permanent neurological injury or death
- Complications of the incision/surgical site, including inflammation, lack of healing, wound dehiscence, transient or persistent pain, seroma, or hematoma
- Infection of the incision/surgical site that could result in sepsis
- Meningitis, encephalitis, or brain abscess resulting from infection involving the brain and/or central nervous system
- Focal edema localized to the area around the lead
- Aseptic intraparenchymal cyst formation around the distal lead tip that may occur weeks to months after implant and may present as new neurological symptoms. Surgical removal of the lead may reduce the size of the cyst and the neurological symptoms caused by cyst formation.
- Erosion of the skin at the lead, extension, or neurostimulator site
- Migration or dislodgement of the lead, extension, or neurostimulator
- Lead, extension, or neurostimulator device complications, including lead or extension fracture, neurostimulator malfunction, neurostimulator setscrews not adequately tightened, and high impedance

- Fibrosis (including tightening, tethering, or bowstringing) at the extension or neurostimulator site may develop weeks to years after implant. It can be associated with pain, disfigurement, limited head mobility, and may require surgical intervention.
- Neurological symptoms, new or exacerbation of existing symptoms which might be transient or permanent, including:
  - vision disorders: diplopia, oculomotor difficulties, or other visual field disorders.
  - speech and swallowing disorders: dysphagia, dysarthria, dysphasia, drooling.
  - motor coordination and balance disorders: akinesia, "freezing," bradykinesia, dyskinesia, paresis, asthenia, muscle spasms/rigidity, tremor, loss of balance/coordination, gait disorder, dizziness, involuntary movements, tics, chorea, dystonia, facial muscle or limb partial paralysis.
  - sensory disturbances: paresthesia, hypoesthesia, burning sensation, headache.
  - mentation impairment: attention or cognitive deficits, dysgraphia, memory disturbances, confusion, somnolence, lethargy.
  - sleep disorders: insomnia, abnormal dreams.
  - déjà vu.
- Psychiatric and behavioral disorders, new or exacerbation of existing symptoms that might be transient or permanent, including:
  - new onset or worsening depression, suicidal ideation, suicide attempt, suicide.
  - anxiety, panic, restlessness.
  - irritability, anger, aggression, agitation.
  - changes or fluctuations in mood, apathy, fatigue.
  - other behavioral manifestations: changes in eating behaviors, obsessive-compulsive disorder, abnormal behavior.
  - hyperactivity or euphoria (hypomania).
  - psychosis, delusions, hallucinations, delirium, disinhibition, perseveration, abnormal thinking.
- New onset seizures during ongoing therapy
- Allergic or immune system response to the implanted materials
- Gastrointestinal disturbances
- Cough associated with DBS
- Transient uncomfortable stimulation (jolting or shocking sensation)
- Lack of effective therapy or loss of therapeutic effect
- Weight gain or loss

If a serious incident related to a patient's therapy occurs, immediately report the incident to Medtronic and the applicable competent authority.

The Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed.

Component disposal

When explanting neurostimulation system components eg, replacement, cessation of therapy, or postmortem , or when disposing of accessories, follow these guidelines:

- If possible, return the explanted component with completed paperwork to Medtronic for analysis and disposal.
- To allow for component analysis, do not autoclave the component or expose the component to ultrasonic cleaners.
- Dispose of any components not returned to Medtronic according to local environmental regulations; in some countries, explanting a battery-operated implantable device is mandatory.

Precautions:

- Follow appropriate biohazard controls for all explanted components or components coming into contact with bodily fluids. Only return such components to Medtronic in the appropriate packaging supplied by Medtronic.
- Do not incinerate or cremate the neurostimulator because it may explode if subjected to these temperatures.

Intended users

The primary users of the implantable devices are implanting and prescribing clinicians who are experienced in deep brain stimulation (DBS) procedures. Implanting clinicians should have expertise with functional stereotactic neurosurgical treatment of DBS-indicated conditions. Such expertise should include knowledge of the anatomical and neurophysiological characteristics of the indicated brain target. They should know surgical or implantation techniques for the DBS neurostimulation system, operational and functional characteristics of the neurostimulation system, and have experience in the continued management of patients by stimulation parameter adjustment. Prescribing clinicians should be experienced in diagnosing and treating DBS-indicated conditions and should be familiar with using the neurostimulation system.

Programming clinicians, under the direction of the implanting or prescribing clinician, may conduct intraoperative test stimulation, program stimulation settings, and assist with use of the patient control device and charging system. MRI clinicians assess the patient's eligibility for an MRI scan and prepare scanning equipment for patients. Medtronic field personnel may provide product assistance and training to clinicians, patients, and caregivers.

Patients are the primary users of patient control devices and charging systems, as they interact with their patient control device to view or adjust their therapy, as prescribed by their DBS clinician. Patients also use a charging system to charge the battery of a rechargeable neurostimulator. Some patients may have a caregiver that assists them with the use of these devices.

Appendix A: Electromagnetic interference (EMI) and mechanical interference

Electromagnetic interference (EMI is a field (electrical, magnetic, or a combination of both) that is generated by various types of equipment or environmental devices found in medical, work, and home environments. These EMI sources may generate enough interference to change the parameters of a neurostimulator, turn a neurostimulator off and on, or cause a neurostimulator to surge, shock, or jolt the patient.

In addition, it is possible for the extension, lead, or both to “pick up” EMI and deliver excess voltage, which can in turn deliver an excessive amount of heat to the brain (or other tissues in contact with the lead or extension .

Refer to the sections that follow for guidelines on the interaction of electromagnetic interference and an implanted brain stimulation system.

Types of EMI

There are 3 categories of EMI, which are generated by medical equipment and devices found in everyday environments for example, home, work, or public places). See Table 1 for a description of these 3 types of EMI.

Table 1. Types of EMI and examples

EMI type	Example
Conductive current—Conducted current flow is introduced by the EMI source or medical equipment touching the body.	For example, conductive current flow in body tissue that is produced between an electrocautery tool and grounding plate.
Induced/coupled current—Current flow introduced by a magnetic or electrical field, where the energy travels through the air (no physical contact). Induced or coupled current may be generated from other medical equipment or EMI source.	For example, inductive current flow could be induced in an implanted lead system by the strong magnetic field of an MRI scan.
Radiated energy—Electromagnetic (EM) radiation is energy traveling through air, named after the manner it is produced: x-rays—produced by tungsten x-ray tubes, gamma rays—produced by radioactive nuclei, etc.	For example, a high energy x-ray beam directed at the electrical circuitry of the implanted neurostimulator can potentially disrupt the neurostimulator output.

All 3 types of EMI can occur alone or in combination, and may interfere with the patient's DBS system by one or more of these events:

- Change or reprogram the neurostimulator parameters
- Turn the neurostimulator on or off

- Cause the neurostimulator to surge, or produce a shocking or jolting sensation to the patient
- Induce or conduct excessive current in the lead or extension system causing tissue damage, including brain tissue damage
- Temporarily suppress the neurostimulator output
- Damage the implanted system components

Reducing the possible effects from EMI

Note: In this manual, references to "turning the neurostimulator off" refer to turning off therapy or stimulation.

Turning the neurostimulator off - A few of the following guidelines recommend that you turn the neurostimulator off (using either the patient or clinician programmer). If the neurostimulator is not turned off, it may be possible for some EMI sources to increase the output amplitude of the stimulation. This could result in patient discomfort, overstimulation effects, and tissue damage, including brain tissue. Turning off the neurostimulator reduces this risk of inductive or coupling EMI.

Note: Even when the neurostimulator is turned off and the neurostimulator stops generating stimulation pulses, the lead and extension are still connected to the neurostimulator and this system could act as a conductive pathway to an EMI source.

The decision to turn off a patient's implanted neurostimulator in order to perform medical diagnostic or therapeutic procedures may result in unforeseen consequences and should therefore be carefully considered based on the patient's underlying medical condition. Consultation with the appropriate medical professionals prescribing or implanting clinicians) is recommended.

Table 2 provides some general information about how to reduce the effects of possible EMI.

Table 2. Reducing the effects of EMI on implanted brain stimulation systems

EMI type	Suggested guidelines
Conductive current	Conductive current follows the path of least resistance. It will diverge between body tissue and any implanted lead system in this path. Keep the implanted neurostimulator and lead system out of the conductive path in order to reduce possible disruptive EMI effects. For example to minimize EMI effects, keep the electrosurgery current flow perpendicular to a line drawn between the neurostimulator case and lead electrodes.

Table 2. Reducing the effects of EMI on implanted brain stimulation systems (continued)

EMI type	Suggested guidelines
Induced/coupled current	The lead system in any implanted system will act as an antenna to electric fields. Any loops formed by the lead system will act as a pickup coil to magnetic fields. The strength of an electric or magnetic field decreases with distance. Increase the distance between an EMI source and the implanted brain stimulation system in order to reduce any possible disruptive EMI effects.
Radiated energy	There is a possibility for high-dose radiation to transiently affect or permanently damage an implanted neurostimulator and lead system. Avoid placing the neurostimulator or lead system directly under the radiating beam.

EMI guidelines for medical procedures

Medtronic neurostimulators are designed to assure immunity from most common sources of EMI. Because many different types of EMI sources exist, it is impossible to specify all interference sources here. The following sections describe the most common sources of EMI along with guidelines on avoiding possible EMI effects.

MR **MR Conditional –** Medtronic DBS Therapy systems have been found to be MR Conditional. Refer to safety information and instructions in the **MRI guidelines for Medtronic deep brain stimulation systems Instructions for use** manual. It is important to read the **MRI guidelines for Medtronic deep brain stimulation systems Instructions for use** manual in its entirety before conducting an MRI examination on a patient with any implanted DBS system component. Scanning under different conditions may result in severe patient injury or device malfunction. Contact Medtronic if you have any questions.

Computed tomography (CT) scan - Ionizing radiation from CT scans will not cause any physical damage to the leads and extensions of an implanted DBS system and is unlikely to cause any physical damage to the neurostimulator. The ionizing radiation produced by a CT scanner induces energy onto an implanted neurostimulator that may cause unintended stimulation. This can result in uncomfortable stimulation or unusual sensations.

If a patient is receiving a CT scan, consider taking these steps to prevent possible changes in stimulation:

- Plan the scan to avoid directly exposing the neurostimulator to ionizing radiation from the CT scanner.
- If the neurostimulator will be directly exposed to ionizing radiation from the CT scanner, turn the neurostimulator off before the CT scan.

- If only the leads or extensions will be directly exposed to ionizing radiation from the CT scanner, the neurostimulator does not need to be turned off.

Diathermy - As detailed in the Contraindications section, injury to the patient or damage to the neurostimulator can occur during diathermy treatment even when:

- the neurostimulation system is turned on or off.
- diathermy is used anywhere on the body—not just at the location of the neurostimulation system.
- diathermy delivers heat or no heat.
- any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body.

Electrocautery - If electrocautery is used near an implantable neurostimulator or touches an implantable neurostimulator, these effects may occur:

- The insulation on the lead or extension may be damaged, resulting in component failure or induced currents into the patient that may damage tissue or stimulate or shock the patient.
- The neurostimulator may be damaged, output may be temporarily suppressed or increased, or stimulation may stop because parameters were changed to power-on-reset settings for example, output off, amplitude 0.0 V .

When electrocautery is necessary, these actions may reduce EMI effects:

- Before using electrocautery, turn off the neurostimulator for all device models.
- Disconnect any cable connecting the lead or extension to a screener or external neurostimulator.
- Use only bipolar cautery.
- If unipolar cautery is necessary:
  - Use only a low-voltage mode.
  - Use the lowest possible power setting.
  - Keep the current path (ground plate) as far away as possible from the neurostimulator, extension, and lead.
  - Do not use full-length operating room table grounding pads.
  - Keep the implanted neurostimulator and lead system out of the conductive path.
  - Keep the electrocautery current flow perpendicular to a line drawn between the neurostimulator case and lead electrodes.

After using electrocautery, confirm that the neurostimulator is functioning as intended.

Laser procedures - Turn off the neurostimulator during laser procedures. Keep the laser directed away from the neurostimulation system. Laser procedures may cause heating, especially at the lead electrode site, resulting in tissue damage.

Additional EMI source examples: Conductive

Bone growth stimulators - Safety has not been established for the use of bone growth stimulators on patients with an implanted DBS System. When using either an implantable or external bone growth stimulator, make sure that both the bone stimulator and the implanted DBS System are working as intended.

Defibrillation or cardioversion - External defibrillation and cardioversion are therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal heart rhythm.

External defibrillation or cardioversion can damage a neurostimulation system and cause induced currents in the lead-extension portion of the system that can injure the patient, including brain tissue damage.

When external defibrillation or cardioversion is required, the first consideration is patient survival. In nonemergent scenarios, refer to Table 3 for recommended neurostimulator settings to perform a cardioversion procedure.

Table 3. DBS System considerations for cardioversion

Device type	Considerations for cardioversion
Percept PC	Ensure MRI mode is off. Program neurostimulator to 0.1 mA, 125 Hz, and 100 µs stimulation. Confirm all active electrode impedances are within a normal range.[a]
Percept RC	Ensure MRI mode is off. Turn off neurostimulator.
Activa PC	Turn off neurostimulator.
Activa RC	Turn off neurostimulator.
Activa SC	Turn off neurostimulator.

[a] Consider a bipolar configuration first to minimize artifact on ECG results.

Minimize the current flowing through the neurostimulation system by following these guidelines:

- Position defibrillation paddles as far from the neurostimulator as possible.
- Position defibrillation paddles perpendicular to the implanted neurostimulation system.
- Use the lowest clinically appropriate energy output [joules (watt seconds)].
- For a cardioversion procedure, wait at least 60 seconds between cardioversion attempts (as clinically appropriate) to allow the neurostimulator to recover.

After a defibrillation or cardioversion procedure, confirm that the neurostimulator is functioning as intended. Contact Medtronic if you have any questions.

Radio-frequency or microwave ablation - Safety has not been established for radio-frequency RF) or microwave ablation in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead-electrode site, resulting in tissue damage, including brain tissue.

Recording procedures - Safety has not been established for recording procedures using equipment that generates electromagnetic interference (eg, electromyography, electroencephalogram, or positron emission tomography) in patients with an implanted DBS System.

Transcutaneous electrical nerve stimulation (TENS) - Do not place TENS electrodes so that the TENS current passes over any part of the neurostimulation system. If patients feel that the TENS may be interfering with the implanted neurostimulator, patients should discontinue using the TENS until they talk with their doctor.

Additional EMI source examples: Inductive

Therapeutic magnets - Therapeutic magnets (for example, those found in bracelets, back braces, shoe inserts and mattress pads) can cause inadvertent on or off activations of the neurostimulator. Therefore, patients should be advised not to use them.

Theft detectors and security screening devices (such as those found in airports, libraries, and some department stores) - Advise patients to use care when approaching theft detectors and security screening devices because these devices can turn their neurostimulator on or off.

When approaching these devices, patients should do the following:

1. If security personnel are present, patients should show them their neurostimulator identification card and request a manual search. Security personnel may use a handheld security wand, but patients should ask the security personnel to avoid placing the wand over the neurostimulator.
2. If patients must pass through the security device, they should approach the center of the device and walk normally (Figure 2.
   - If two security gates are present, they should walk through the middle, keeping as far away as possible from each gate.
   - If one gate is present, they should walk as far away as possible from it.

   Note: Some theft detectors may not be visible.
3. Patients should proceed through the security device. Patients should not touch, lean on or linger near the security device.

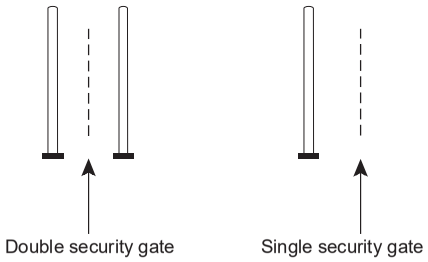

Figure 2. *Approaching security gates.*

4. If patients suspect that their neurostimulator was turned off, they should make sure someone is able to turn on the system again. (This person could be the patient, if his or her medical condition allows it. It could also be a family member or clinician who has been taught how to use the system.)

Additional EMI source examples: Conductive and inductive

Home appliances - Home appliances that are in good working order and properly grounded do not usually produce enough electromagnetic interference (EMI) to interfere with neurostimulator operation. However, items with magnets (eg, stereo speakers, refrigerators, freezers, power tools) may cause the neurostimulator to switch on or off.

Occupational environments - Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough electromagnetic interference (EMI) to interfere with neurostimulator operation if approached too closely.

Additional EMI source examples: Radiation

Radiation therapy - High-radiation sources should not be directed at the neurostimulator. High-radiation exposure may temporarily interfere with neurostimulator operation and may damage the neurostimulator. Damage may not be immediately apparent. To limit device exposure, use appropriate shielding or other measures, such as making beam angle adjustments to avoid the device.

Mechanical interference

Mechanical interference can be defined as interference that is caused by pressure waves generated by vibrating transducers used in imaging (ie, diagnostic ultrasound) or surgical procedures such as lithotripsy. The mechanical motion of the actual transducers may also be a source of interference.

Diagnostic ultrasound - Diagnostic ultrasound poses no electrical interference problems for the DBS System, however the transducer should not be placed directly over the implanted neurostimulator.

Lithotripsy - Use of high output ultrasonic devices, such as an electrohydraulic lithotriptor, is not recommended for patients with an implanted DBS System. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam within 15 cm (6 in) of the neurostimulator.

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Medtronic

Medtronic Deep Brain Stimulation Therapy for Movement Disorders

Indication-specific information
for implantable neurostimulators

Information for prescribers addendum

! USA Rx only

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Information available for the Deep Brain Stimulation Therapies:

The information for prescribers manual provides information about contraindications, warnings, precautions, adverse events, sterilization, and component disposal. The information for prescribers addendums contain indication-specific information. For customers in Japan, the appropriate package insert provides information about safety, contraindications, warnings, precautions, and adverse events.

The indications sheet provides information about indications and related information. For customers in Japan, the appropriate package insert provides information about indications.

The system eligibility and battery longevity manual describes programming considerations and provides battery longevity information to aid in the appropriate neurostimulator selection.

MRI guidelines provide information about any MRI conditions and MRI-specific contraindications, warnings, and precautions for MRI scans with the neurostimulation system.

Product manuals, such as programming guides, recharging guides, and implant manuals provide device descriptions, package contents, device specifications, product-specific warnings and precautions, and instructions for use.

! USA **The clinical summary provides information about the clinical study results for the neurostimulation system.**

Contraindications

There are no therapy-specific contraindications for Medtronic Deep Brain Stimulation (DBS) Therapy for Movement Disorders. Refer to the primary DBS Information for prescribers manual for common DBS contraindications.

Warnings

Programming at low frequencies - The use of rates less than 30 Hz may “drive” tremor, that is, cause it to occur at the same frequency as the programmed frequency. For this reason, rates should not be programmed below 30 Hz. Refer to the primary DBS Information for prescribers manual for more information about excessive stimulation.

Return of symptoms and rebound effect - Inform patients and their caregivers that abrupt cessation of stimulation for any reason, including failure to maintain adequate battery charge in rechargeable neurostimulators, will probably cause a return of disease symptoms. In some cases, symptoms may return with an intensity greater than was experienced prior to system implant rebound effect). This can in rare cases constitute a medical emergency. For patients with rechargeable neurostimulators, it is important that the clinician emphasize the following:

- Patients must be willing and able to perform battery status checks and battery recharge activities on a frequent basis.
- The device charge level should be maintained such that symptoms are controlled.
- The recharge warnings from the patient control device must be understood and heeded by the patient and caregiver.
- Medication may aid in symptom control during short periods of time following depletion of the device before a recharge session.

If symptoms worsen or do not abate following recharge, the patient should contact his or her clinician immediately so the status of the system can be assessed and the condition of the patient can be monitored.

Importance of regular recharging (rechargeable neurostimulator only) - Inform patients and their caregivers that it is important to maintain a regular schedule of recharging.

Risk of depression, suicidal ideations, and suicide - New onset or worsening depression which may be temporary or permanent is a risk that has been reported with DBS therapy. Suicidal ideation, suicide attempts, and suicide are events that have also been reported. Therefore, clinicians should consider the following:

- Preoperatively, assess patients for the risks of depression and suicide. This assessment should consider both the risk of depression and suicide as well as the potential clinical benefits of DBS therapy for the condition being treated.
- Postoperatively, actively monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control.
- If a patient experiences new or worsening depression or suicidal ideation, manage these symptoms appropriately.

- Educate patients and caregivers about these potential risks prior to implantation, and be sure that they know about the importance of ongoing support and follow-up, including when to contact their health care provider.

Precautions

Clinician training

Prescribing clinicians - Prescribing clinicians should be experienced in the diagnosis and treatment of movement disorders and should be familiar with the use of the Medtronic DBS System for Movement Disorders.

Implanting clinicians - Implanting clinicians should have expertise with functional stereotactic neurosurgical treatment of movement disorders. Such expertise should include knowledge of the anatomical and neurophysiological characteristics of the targeted nucleus, surgical and/or implantation techniques for the Medtronic DBS System for Movement Disorders, operational and functional characteristics of the Medtronic DBS System for Movement Disorders, and experience in the continued management of patients by stimulation parameter adjustment.

Clinicians may contact Medtronic before prescribing or implanting a Medtronic DBS System for Movement Disorders for the first time and request a referral to a clinician experienced in the use of Medtronic DBS Therapy for Movement Disorders.

Prescribing and implanting clinicians of rechargeable neurostimulation systems should be aware of the patient requirements for a rechargeable neurostimulator. Refer to the primary DBS Information for prescribers manual for the patient requirements for rechargeable neurostimulators.

All programming of the Medtronic DBS System for Movement Disorders should be performed by or under the supervision of a clinician or other experienced medical personnel familiar with the use of the programming software and equipment. Clinicians should be thoroughly familiar with the supporting material for the Medtronic DBS System for Movement Disorders, including all product labeling and education and training materials.

System implant

Battery longevity and brain target selection - Stimulation settings for systems implanted in the internal globus pallidus (GPi) may be higher than stimulation settings for systems implanted in the subthalamic nucleus (STN). Consequently, when implanted in the GPi, rechargeable systems may need to be charged more frequently and nonrechargeable systems may have reduced battery longevity compared to systems implanted in the STN.

Lead placement confirmation

Implantation of a DBS system should only occur after confirmation of successful lead placement at the targeted nuclei by either intraoperative test stimulation or confirmatory imaging.

Long-term safety and effectiveness

Long-term safety and effectiveness - The long-term safety and effectiveness of Medtronic DBS Therapy for Movement Disorders has not been established beyond 36 months.

Intraoperative test stimulation

Intraoperative test stimulation for DBS Therapy is intended as an aid in lead placement and neurostimulator selection for movement disorder therapies.

For operating instructions on the Model 37022 External Neurostimulator (ENS , refer to the ENS manual and to the applicable clinician programming guide.

Verifying neurostimulator selection during test stimulation

Verify that the appropriate neurostimulator for the patient will be implanted by following these guidelines:

- Select screening settings that do not exceed the clinician programmer high-output interlock limit for the intended neurostimulator, if applicable.
- Verify that the parameter settings used to achieve therapeutic benefit are outside the charge density warning area.
- Verify that the test stimulation parameter results are within the range available for the intended neurostimulator.

Notes:

- Identify if independent rate control is required to provide symptom control for your patient. If independent rate control is required, either select a device that supports multiple rates, or select a single program device.[1]
- For complete information, see the system eligibility and battery longevity manual.

Checking for symptom suppression during test stimulation

Note the following when determining the effectiveness of test stimulation:

- If the VIM is the targeted nucleus, the desired stimulation effect is an obvious suppression of tremor. Other stimulation effects that may aid in placement of the lead, but may not be desirable, include paresthesia, especially in the hand and around the mouth.

[1] In Medtronic clinical studies of the Itrel II Model 7424 Neurostimulator for advanced Parkinson$_S$ disease, at least 58% of all subjects had identical rates bilaterally at all follow-up visits.

- If the GPi or STN is the targeted nucleus, the desired stimulation effect is the obvious suppression of a predominant Parkinson's disease symptom, such as rigidity, bradykinesia, or tremor. Neurological assessments such as the passive movement of joints, finger tapping, hand movements, or holding and drinking from a ceramic cup can be administered to evaluate the effects of stimulation on Parkinson's disease symptoms. Other stimulation effects that may aid in placement of the lead in the STN, but are not desirable, include initiation of dystonia and choreic dyskinesias. Other stimulation effects that may aid in placement of the lead in the GPi, but are not desirable, include new onset of visual field effects and dystonia.

Postoperative patient programming

The treating clinicians should be experienced in all aspects of the medical management of patients with Parkinson's disease or essential tremor. Clinicians using Medtronic DBS Therapy for the first time are encouraged to contact a Medtronic representative for information on the postoperative management of patients with Medtronic DBS Therapy.

When programming stimulation parameters, consider the following recommendations on initial stimulation parameters.

Programming initial stimulation parameters for Medtronic DBS Therapy for Parkinson’s Disease

This procedure instructs on programming postoperative stimulation parameters for Medtronic DBS Therapy for Parkinson’s Disease and is one approach for the clinician$_S$ consideration.

High amplitude and pulse width combinations can result in excessive charge density.

1. Allow sufficient time for the patient to recover from surgery. Schedule the initial programming visit so that the patient is in an “off” period, when the Parkinson’s disease symptoms are predominant.
2. Set the neurostimulator to the initial settings provided in Table 1.
3. To evaluate the potential effectiveness of all electrodes, select a predominant Parkinson’s disease symptom, such as rigidity or tremor, that responds to changes in stimulation.

Table 1. Programming settings for Medtronic DBS Therapy for Parkinson's Disease

Parameters	Typical initial setting	Range or options	Typical final setting[a]
Activa devices			
Amplitude (Voltage)	0.0 V	Normal 0 to 10.5 V 0.1 V or 0.05 V steps	2.5 to 3.5 V[b]
Amplitude (Current	0.0 mA	0 to 25.5 mA 0.1 mA steps	2 to 3 mA[c]
Pulse width	60 to 120 µs	60 to 450 µs 10 µs steps	60 to 120 µs
Rate	130 to 160 Hz	2 to 250 Hz Constant current: 30 to 250 Hz	130 to 185 Hz
Electrode polarity	Unipolar (Case positive 0 lead electrode negative	Unipolar or bipolar	Varies[d]
Mode	Continuous	Not applicable	Continuous
Percept devices			
Amplitude	0.0 mA	Normal 0 to 25.5 mA 0.1 mA steps (0 to 25.5 mA 0.05 mA steps (0 to 12.5 mA	2 to 3 mA[c e]
Pulse width	60 to 120 µs	20 to 450 µs 10 µs steps	60 to 120 µs
Rate	130 to 160 Hz	2 to 250 Hz	130 to 185 Hz

Table 1. Programming settings for Medtronic DBS Therapy for Parkinson's Disease (continued)

Parameters	Typical initial setting	Range or options	Typical final setting[a]
Electrode polarity	Unipolar (Case positive 0 lead electrode negative	Unipolar or bipolar	Varies
Mode	Continuous	Not applicable	Continuous

[a] These settings are based on leads without segmented electrodes and may not apply to directional leads.

[b] If programming one or more segments of a directional lead, start at a conservatively low setting for each segment and ramp up toward the typical final setting shown in the table.

[c] Based on a conversion of the constant voltage range to constant current, using an impedance of 1200 ohms.

[d] In the Medtronic-sponsored clinical investigation, most STN patients used unipolar stimulation, whereas similar proportions of GPi patients used unipolar and bipolar stimulation.This investigation did not include directional leads.

[e] If programming one or more segments of a directional lead, start at a conservatively low setting for each segment and ramp up toward approximately one third (1/3) of the typical final setting shown in the table.

4. To expedite electrode selection, program the neurostimulation system to a unipolar electrode configuration where the neurostimulator case is the positive electrode and electrode 0 is the negative electrode.
5. Gradually increase amplitude incrementally until a predominant Parkinson's disease symptom (rigidity, tremor) is suppressed. Record screening results.
6. If there is uncomfortable stimulation or inadequate symptom suppression, reduce the amplitude to 0 (V or mA) and select another electrode as the negative electrode. Repeat step 5. Select the electrode that provides the best control of symptoms with the fewest side effects.
7. After the most desirable negative electrode is selected, gradually increase the amplitude until side effects occur. The therapeutic window between symptom suppression and occurrence of side effects should be sufficiently wide to allow for future amplitude adjustments.
8. Evaluate the patient in an "on" period, when Parkinson's disease symptoms are controlled after a usual dose of antiparkinson medication. Assess the effect of stimulation on suppressing or worsening of dyskinesias.
9. After amplitude settings are determined, adjust pulse width and rate to improve therapeutic benefit and minimize side effects.

   Note: Symptom suppression is desirable at the lowest possible amplitude, rate, and pulse width to improve battery longevity and minimize charge density.

10. Document final parameter settings for future reference.

Programming initial stimulation parameters for Medtronic DBS Therapy for Essential Tremor

This procedure instructs on programming postoperative stimulation parameters for Medtronic DBS Therapy for Essential Tremor and is one approach for the clinician's consideration.

1. Allow sufficient time for the patient to recover from surgery.
2. Set the neurostimulator to the initial settings provided in Table 2.
3. Program the neurostimulation system to a bipolar electrode configuration, where electrode 0 is the negative electrode and electrode 3 is the positive electrode.

Table 2. Programming settings for Medtronic DBS Therapy for Essential Tremor

Parameters	Typical initial setting	Range or options	Typical final setting[a]
Activa devices			
Amplitude (Voltage)	0.0 V	Normal 0 to 10.5 V 0.1 V or 0.05 V steps	1 to 3 V[b]
Amplitude (Current	0.0 mA	0 to 25.5 mA 0.1 mA steps	0.8 to 2.5 mA[c]
Pulse width	60 µs	60 to 450 µs 10 µs steps	60 to 90 µs
Rate	130 Hz	2 to 250 Hz Constant current: 30 to 250 Hz	130 to 185 Hz
Electrode polarity	Bipolar (0 electrode negative 3 electrode positive Case off)	Unipolar or bipolar	Bipolar
Mode	Continuous	Not applicable	Continuous
Percept devices			

Table 2. Programming settings for Medtronic DBS Therapy for Essential Tremor (continued)

Parameters	Typical initial setting	Range or options	Typical final setting[a]
Amplitude	0.0 mA	Normal 0 to 25.5 mA 0.1 mA steps (0 to 25.5 mA 0.05 mA steps (0 to 12.5 mA	0.8 to 2.5 mA[c] [d]
Pulse width	60 µs	20 to 450 µs 10 µs steps	60 to 90 µs
Rate	130 Hz	2 to 250 Hz	130 to 185 Hz
Electrode polarity	Bipolar (0 electrode negative 3 electrode positive Case off)	Unipolar or bipolar	Bipolar
Mode	Continuous	Not applicable	Continuous

[a] These settings are based on leads without segmented electrodes and may not apply to directional leads.

[b] If programming one or more segments of a directional lead, start at a conservatively low setting for each segment and ramp up toward the typical final setting shown in the table.

[c] Based on a conversion of the constant voltage range to constant current, using an impedance of 1200 ohms.

[d] If programming one or more segments of a directional lead, start at a conservatively low setting for each segment and ramp up toward approximately one third (1/3) of the typical final setting shown in the table.

4. Gradually increase amplitude until the occurrence of uncomfortable stimulation or the suppression of tremor is observed. Record screening results.
5. If there is uncomfortable stimulation or inadequate tremor suppression, reduce the amplitude to 0 (V or mA) and select another electrode as the negative electrode. Repeat step 4. Select the electrode that provides the best control of tremor with the fewest side effects.
6. After the desirable negative electrode is selected, gradually increase the amplitude until side effects occur. The therapeutic window between tremor suppression and occurrence of side effects should be sufficiently wide to allow for future amplitude adjustments.

7. After amplitude settings are determined, adjust pulse width and rate to improve therapeutic benefit and minimize side effects.

   Note: Tremor suppression is desirable at the lowest possible amplitude, rate, and pulse width to improve battery longevity, and minimize charge density.
8. Document final parameter settings for future reference.

Adverse events

For potential adverse events related to DBS therapy, refer to the primary DBS Information for prescribers manual.

There are no known additional therapy-specific adverse events associated with DBS Therapy for Movement Disorders.

! USA For adverse events reported in the Parkinson's disease and essential tremor clinical studies, refer to the clinical summary.

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