Clinician Programmer Application for Deep Brain Stimulation

A610

Clinician Programming Guide
Activa™ Model 37601, 37602, 37603, and 37612 Neurostimulators
Model 37022 External Neurostimulator

Application version 2.0

! USA Rx only

CE 0123
2020

Medtronic

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

CE 0123 Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123).

! USA For USA audiences only

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 indications, safety, contraindications, warnings, precautions, and adverse events.

The indications sheet provides information about indications and related information.

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.

Refer to the Model 8880T2 Communicator technical manual for warnings, precautions, device description, package contents, device specifications, instructions for use, and maintenance information.

Refer to the literature provided by the Clinician Tablet manufacturer for information regarding wireless use.

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

TABLE OF CONTENTS

DEVICE DESCRIPTIONS AND INTENDED USES

Model A610 Clinician Programmer Application

The Medtronic™ Model A610 DBS Clinician Programmer Application (app) is intended for use by clinicians in the programming of Medtronic neurostimulators (external and implantable) for deep brain stimulation (DBS).

Of the neurostimulators for which the Model A610 Clinician Programmer Application is intended, this programming guide is for use with the following:

- Activa™ PC Model 37601 Implantable Neurostimulator (INS)
- Activa SC Model 37602 Implantable Neurostimulator (INS)
- Activa SC Model 37603 Implantable Neurostimulator (INS)
- Activa RC Model 37612 Implantable Neurostimulator (INS)
- Model 37022 External Neurostimulator (ENS)

Note: Programming information for the Percept™ PC Model B35200 Implantable 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” on page 48 for instructions on using the Patient Data Service app.

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” on page 40.

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.

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 it.

Data security

Data is protected by application-level encryption and encryption provided by the tablet. The app does not provide data protection for data exported to another destination. Data exported from the app should be handled in accordance with your facility’s security policy for data handling and storage.

To protect your clinician programmer system, Medtronic recommends you implement the following security measures:

- Always save data exported from the app to the default location.
- Use a managed, trusted Wi-Fi® connection when network connectivity is needed.
- Consider securing your tablet by disabling network connectivity during any programming session.

If you suspect a cybersecurity event has occurred, stop using the app (if possible) and contact your IT Security or Medtronic Technical Services to document and respond to the suspected incident.

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 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.

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.

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 check 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” on page 39.
- **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” on page 47.
- **About –** View detailed information about the neurostimulator, communicator, patient control device, and clinician tablet. For more information, see “ABOUT SCREEN” on page 49.
- **Preferences –** View and modify various settings and options that are indication-specific. These preferences endure beyond an individual programming session. For more information, see “Total with Cycling Reset off” on page 50.
- **Usage –** View statistics about patient’s use of the system. For more information, see “USAGE SCREEN” on page 46.

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® 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.
	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 to 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 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.

   Notes:

   - 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.
   - 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” on page 21 for information about configuring and programming the INS.

Refer to “Communicator and tablet troubleshooting” on page 50 for troubleshooting problems related to the communicator.

USING THE EXTERNAL NEUROSTIMULATOR (ENS)

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

When programming during test stimulation, hold the clinician programmer communication device (eg, programming head, communicator) over the external neurostimulator. The external neurostimulator can also be attached to the programmer communication device.

Setting up the ENS

When connected to an external neurostimulator, the **SETUP** task is a process that enables you to set up the external neurostimulator for intraoperative programming and testing.

The **SETUP** task can also be used to edit existing information that was entered during initial setup.

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. Tap the plus icon (+) to select the component that connects to the external neurostimulator.
3. Tap **UPDATE** in the bottom-right corner to complete the task and return to the **HOME** screen.

Programming the ENS

Intraoperative programming allows you to adjust settings on the Model 37022 External Neurostimulator delivered via a screening cable.

For general information about programming, refer to “To program” on page 22.

For information on charge density, refer to “CHARGE DENSITY” on page 16.

For information on out-of-range limitations, refer to “HIGH-OUTPUT INTERLOCKS OR STIMULATION SETTINGS OUT OF RANGE (OOR)” on page 18.

There are additional considerations for intraoperative programming:

- Stimulation capabilities may be lower than those of the implantable neurostimulator.
- Groups, patient limits, cycling, interleaving, and annotations are not available.
- Settings are not saved from session to session.

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 Programming screen.

2. Adjust programming settings using the controls on the Programming screen:

    a. **Electrode configuration (twist-lock screening cable only) –** Tap an electrode to change its polarity. Select at least one negative (⊖) and one positive (⊕) electrode. Tap **UPDATE** when you are done.

    b. **Parameter tabs –** These three tabs allow switching the programmable parameter between amplitude, pulse width, and rate.

    c. **Controls –** Adjust the selected stimulation parameter using any of the following controls.

        – Press, hold, 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.

        Notes (amplitude only):

        – 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.

        – Tap the Settings button (⚙) at the right of the vertical slider bar to change the resolution of the control to 0.05 increments (voltage mode only).

TURNING STIMULATION ON OR OFF

At any time, you can turn stimulation on () or off () using the toggle at the top-right corner of the screen.

Note: While on the **MRI ELIGIBILITY** results screen, you cannot turn stimulation on or off. See “To exit MRI ELIGIBILITY results screen” on page 37.

SETTING UP THE INS

This section is for setting up an implantable neurostimulator. For information on setting up an external neurostimulator, refer to “Setting up the ENS” on page 13.

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.

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. (Optional) On the **Patient** screen, enter the patient and physician information.

   Notes:

   – 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** to continue.
4. 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.
5. Tap **Yes** or **No** to indicate whether the patient is on medication during evaluation.
6. (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.
7. (Optional) Select the pencil icon (✎) on an existing symptom to edit or delete that symptom.
8. Tap **UPDATE** to continue.
9. On the **Components** screen, use the dropdown list to select the location of the neurostimulator.

   Note: If no pocket adaptors are implanted, then check the checkbox below **ADAPTORS**.
10. 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 (↓↑).
- Take notice of the electrode numbers associated with each lead location, to aid in confirming system connection.

11. Tap **UPDATE** to continue.
12. On the **Other** screen, tap the check box indicating whether the patient has any abandoned deep brain stimulation system components.
13. Tap **UPDATE** to continue.
14. 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.
15. Tap **DONE** in the bottom-right corner 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:

- In voltage mode, the delivered current depends on the therapy impedance.
- In current mode, the delivered current remains constant regardless of impedance.

Charge density in voltage mode

When programming parameters using voltage mode, the charge density threshold varies depending on whether an electrode impedance test has been performed in the current programming session, and depending on what amplitude was used during the test:

- By default, charge density is calculated using a conservative impedance value of 500 ohms (see Figure 1).
- If an electrode impedance test has been performed in this programming session, and 3.0 volts was used during the test, charge density is calculated using the measured impedance.

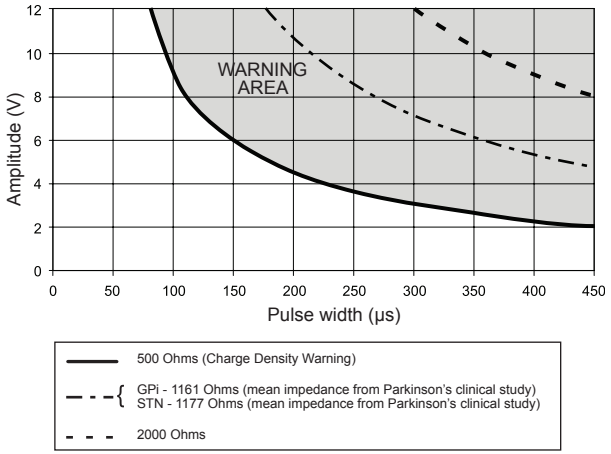


Figure 1. Charge density using impedance values from clinical studies.

The first time the programmed therapy settings result in a charge density that exceeds the charge density threshold, the Charge Density Warning appears.

Note: If patient limits are programmed, the upper limit settings for amplitude and pulse width are always used in the charge density calculation.

If you wish to proceed with the programming change, check the check box in the warning message to confirm, then tap the **OK** button to continue.

When settings exceed the charge density threshold, the programmed stimulation value, as well as the Volume of Neuronal Activation (VNA) model, will display as orange in color.

Charge density in current mode

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.

HIGH-OUTPUT INTERLOCKS OR STIMULATION SETTINGS OUT OF RANGE (OOR)

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

High-output interlocks (voltage mode)

The programmer will restrict certain combinations of high amplitude, pulse width, and rate parameters from being selected.

To achieve a high parameter setting, reduce the other parameter values. For example, if high amplitude is desired, reduce the rate or the highest pulse width within the group.

Note: If the upper limit for amplitude, pulse width, or rate is programmed to a higher value than the programmed value, the programmer will use this value when determining the high-output interlock.

Stimulation Settings Out Of Range (current mode)

Certain combinations of amplitude, pulse width, and rate settings are too high for the system to provide in a low-battery-level 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 the stimulation parameter until the out-of-range alert disappears.
- To achieve a high parameter setting, 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” on page 52.

SEIZURE DATA (EPILEPSY ONLY)

About seizure data

Epilepsy patients have the ability to record seizure events and reset their stimulation cycle using the patient control device. These events are available for review on the clinician programmer app.

Note: Use the patient control device to select whether the patient can reset the stimulation cycle.

How to read data from the Seizure key

Data from the **Seizure** key, recorded on the patient control device, appears as two lines of text on the Clinician Notes section of the **HOME** screen. The first row displays data from the **Seizure** key with Cycling Reset turned on. The second row displays data from the **Seizure** key with Cycling Reset turned off.

The sample data shown in Figure 2 indicates that the patient initiated a seizure recording a total of 37 times since the last programming session. It was pressed 37 times with Cycling Reset turned on, and 6 times with Cycling Reset turned on and stimulation turned off. It was pressed 0 times with Cycling Reset off, and 0 times with both Cycling Reset off and stimulation off.

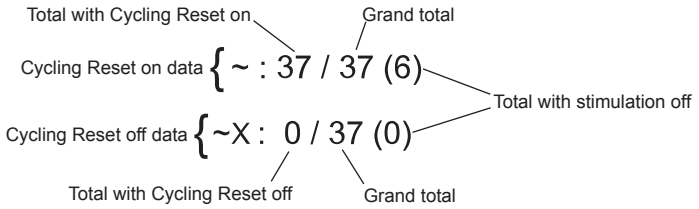


Figure 2. Sample data from the Seizure key.

Compare the data from the **Seizure** key to data observed during the patient's last programming session. Identical numbers could indicate that the patient has not been using the **Seizure** key. You should also compare the data from the **Seizure** key to the patient's paper seizure log. When finished reviewing the data from the **Seizure** key, reset the **Seizure** key count to zero. Refer to "How to reset the patient control device seizure count to zero" on page 19 for more information.

Note: If more than one patient control device has been used to record a seizure event since the last programming session, only the data from the patient control device that was used last will appear.

How to reset the patient control device seizure count to zero

For both the clinician programming system and the patient control device, the data from the Seizure key can be reset to zero by ending a programming session.

For information on how to end a programming session, refer to "ENDING A SESSION" on page 40.

Setting seizure mode (Model 37441 Patient Programmer only)

On designated patient control devices, the **Seizure** key records a seizure event every time it is pressed. It can be set up to reset Cycling and record a seizure event (Cycling Reset on) or to record a seizure event only (Cycling Reset off) every time it is pressed. The **Seizure mode set up** screen displays the active mode at the top of the screen. The icons at the bottom of the screen allow the user to change the setting.

Note: The **Seizure** key functions the same in **Simple** mode, **Advanced View** mode, and **Advanced Adjust** mode.

To set Seizure mode using the Medtronic Intercept™ Model 37441 Patient Programmer

1. Press the **Power/Backlight On/Off** key to turn on the patient control device (Figure 3).
2. Press and hold the **Selection** keys (Figure 3) at the same time until the next screen appears. The lead connections screen is displayed on the patient control device.

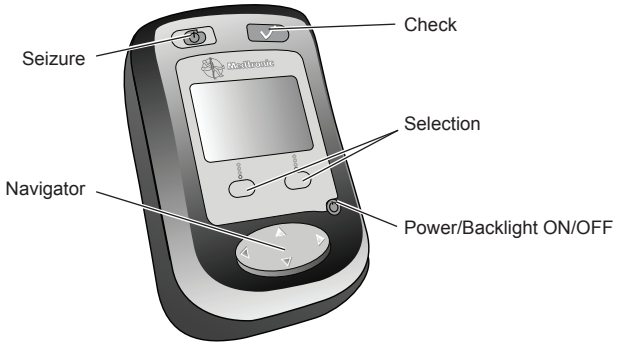


Figure 3. Patient programmer keys.

3. Press the left or right arrow on the **Navigator** key until you reach the **Seizure mode set up** screen (Figure 4).

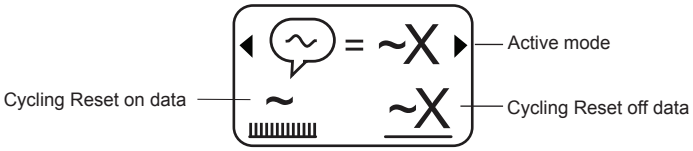


Figure 4. Seizure mode set up screen.

4. Press the appropriate **Selection** key (Figure 3) to set the Seizure mode to record a seizure event and reset Cycling (Cycling Reset on [~]) or to record a seizure event only (Cycling Reset off [~X]) each time the **Seizure** key is pressed.
5. The active mode appears at the top of the patient control device screen.
6. Press the **Power/Backlight On/Off** key to turn off the patient control device (Figure 3).

PROGRAMMING THE INS

About programming

Note: When changing therapy parameter settings, increase or decrease in small increments while evaluating the patient's response. See "ANNOTATIONS" on page 26 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 volts (V) or milliamps (mA).
  - **Pulse width:** Duration of each pulse in microseconds (µs).
  - **Rate:** Frequency of pulses in hertz (Hz). Rate is the same value across all programs in a group.

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.

- **Cycling:** Turns stimulation on and off at clinician-determined intervals.
- **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" on page 29.
- **SoftStart/Stop™:** 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.

For information on changing the default values of settings, refer to "PREFERENCES SCREEN" on page 50.

Notes about programming:

- Using the lowest effective amplitude and pulse width minimizes the charge density, the amount of stimulation applied to the patient over a given surface area. If programming reaches charge density limits, an alert will appear. For more information on charge density, refer to "CHARGE DENSITY" on page 16.
- For Activa PC or Activa SC, using the lowest effective amplitude and pulse width may increase battery longevity. For Activa RC, 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” on page 23.

- Increasing the amplitude takes effect gradually when ramping to the target value. Ramping can be adjusted or turned off 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.

   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. Adjust programming settings using the following controls on the Programming screen (Figure 5).
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.

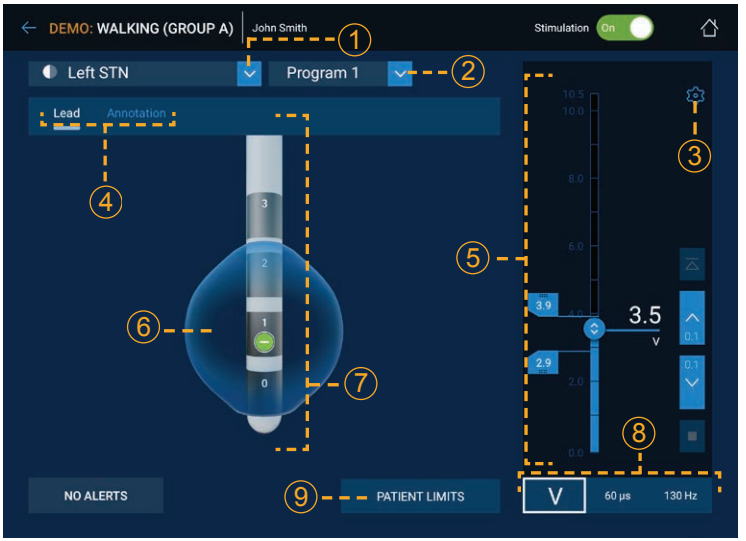


Figure 5. The Programming screen.

①	**Lead location dropdown list –** Select a lead location.
②	**Program dropdown list –** Select a program.
③	**Settings button –** Tap to access additional programming settings.
④	**Navigation tabs –** Tap to view another screen.

⑤	**Controls –** Adjust the selected stimulation parameter using either of the following controls: ■ 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.
⑥	**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.
⑦	**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.
⑧	**Parameter tabs –** Select the parameter to be programmed: amplitude, pulse width, or rate.
⑨	**PATIENT LIMITS button –** Tap to access patient limit modes and options.

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 6 on page 24.

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

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 6).
   - **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.
- **To delete a group or program:** Press, hold, and drag a group or program to the Trash slot (🗑).

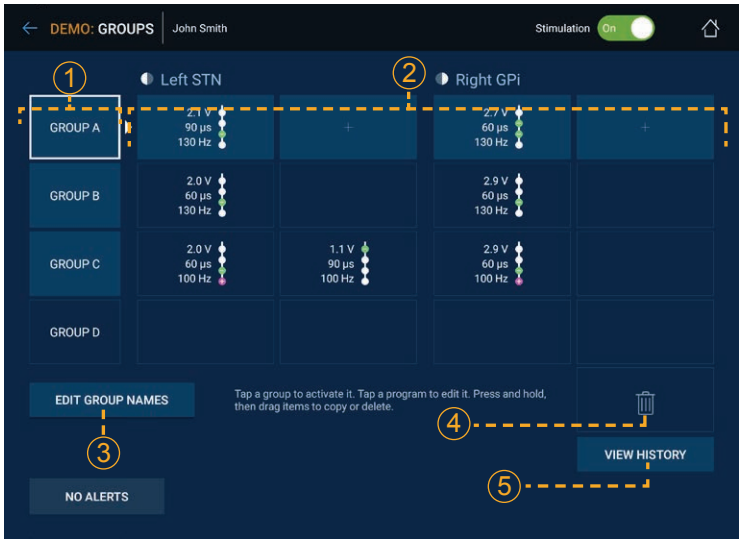


Figure 6. The GROUPS screen.

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.
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" on page 24.

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:

- When in constant voltage mode, interleaved programs can share a maximum of one active electrode.
- Amplitudes and pulse widths may be the same or they may differ between interleaved programs.
- Rate, rate limits, SoftStart/Stop, and cycling are always the same between interleaved programs.

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” on page 22.

   Note: Interleaving programs must have the same rate, which cannot exceed 125 hertz. Once set up, rate adjustments of one program affect the rate of the entire group.

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” on page 23.

   Note: Interleaving programs must have the same rate, which cannot exceed 125 hertz. Once set up, rate adjustments of one program affect the rate of the entire group.

ANNOTATIONS

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

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.[1]

   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” on page 15 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.[1]

   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” on page 15 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 (✎).

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.

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

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.

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 allows the patient to view their stimulation level, and to switch between multiple groups.
  - **Advanced View** mode is automatically selected if you configure a second group while in **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 7).

Figure 7. The Patient Limits screen.

①	**PATIENT LIMITS button –** Allows access to Patient Limits modes and settings.
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.
③	**Settings button –** Allows you to adjust the program to which patient limits are applied: **Program 1**, **Program 2**, or **Both**.

Notes:

- When adjusting the limits for two programs, adjusting the limits of one program may automatically adjust the limits of the other program. When on the **Lead** tab, the limits of the other program are shown in real time, to the left of the vertical slider bar.
- 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” on page 16 for more information.

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 **CHECK BATTERY REMINDER**.
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)” on page 42.

For information on post-implant troubleshooting related to unexpected impedance values, see “ELECTRODE IMPEDANCE TROUBLESHOOTING (POST-IMPLANT)” on page 43.

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” on page 32.

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

This section explains how to perform an electrode impedance test. For information on performing a therapy impedance test, see “To perform a therapy impedance test” on page 33.

There are options when you run an electrode impedance test:

- **Single amplitude (0.7 V, 1.5 V, or 3.0 V)**

  If you select a single amplitude, that amplitude will remain constant for the duration of the test.

- **Automatic increase**

  If you select **Automatic increase**, the system will automatically start with 0.7 volts for the test. The system may automatically increase to 1.5 volts, and then may increase to 3.0 volts, to complete the test.

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

Amplitude	Pulse width	Rate
0.7 V	80 µs	100 Hz
1.5 V	80 µs	100 Hz
3.0 V	80 µs	100 Hz

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. Use the dropdown list to select the amplitude option for the impedance test, then tap **START** to continue.
5. Follow the on-screen prompts. When the impedance measurement is complete, the results appear on the **IMPEDANCE** screen (Figure 8).

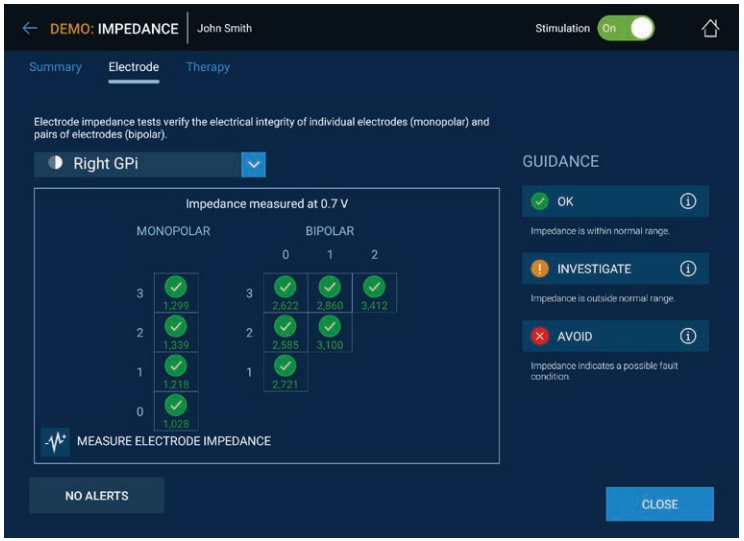


Figure 8. Electrode Impedance Results screen (post-test).

6. 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” on page 42.
   - For more information on post-implant troubleshooting, refer to “To troubleshoot post-implant using electrode impedance measurements” on page 44.

To perform a therapy impedance test

This section explains how to perform a therapy impedance test. For information on performing an electrode impedance check, see “To perform an electrode impedance test” on page 32.

Note: During the therapy impedance measurement, the neurostimulator will automatically use the parameters of the programs within the active group.

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 **Therapy** tab.
3. Tap the **MEASURE THERAPY IMPEDANCE** button (∿).
4. Review the results.

   Notes:

   - Refer to the descriptions under **GUIDANCE** for more information on understanding high and low impedances.
   - Tap on any of the descriptions under **GUIDANCE** for more information.

- For more information on intraoperative troubleshooting, refer to “To troubleshoot intraoperatively using electrode impedance measurements” on page 42.
- For more information on post-implant troubleshooting, refer to “To troubleshoot post-implant using electrode impedance measurements” on page 44.
- The amplitude values listed under the therapy impedance values can be used to help estimate battery longevity. For more information, refer to the system eligibility battery longevity reference manual.

MRI ELIGIBILITY OF THE DBS SYSTEM

About MRI eligibility

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 an MRI eligible state.

To check MRI eligibility and enter MRI eligible state

When using the clinician tablet to confirm 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.

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 eligible 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 the **MRI ELIGIBILITY** results screen, 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 Scan-Type 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 Scan-Type Eligibility Report while on the **MRI ELIGIBILITY** results screen.
8. Tap **ENTER MRI CONFIGURATION** to enter the **MRI ELIGIBILITY** results screen with the selected stimulation option.

To exit the **MRI ELIGIBILITY** results screen, tap **EXIT MRI CONFIGURATION** in the bottom-right corner of the **MRI ELIGIBILITY** results screen.

Interpreting MRI eligibility results

On the **MRI ELIGIBILITY** results 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 3.

Table 3. 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 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 entered correctly in the app?
- Is there an impedance issue? If so, refer to “To troubleshoot intraoperatively using electrode impedance measurements” on page 42 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 ELIGIBILITY** results 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” on page 36.

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” on page 34.

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 4.

Table 4. 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.
	**Download button –** to download and save the report on the clinician tablet.
	**Delete button –** to delete the report.

To exit MRI ELIGIBILITY results screen

To exit the **MRI ELIGIBILITY** results screen, tap **EXIT MRI CONFIGURATION** in the bottom-right corner of the 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 5 for specific outcomes.

Table 5. Outcomes for REPLACEMENT workflow

Source	Destination	Outcome
Percept PC	Percept PC	Transfers settings
	Activa RC	Not available
	Activa PC	Not available
	Activa SC	Not available
Activa RC	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 PC	Transfers settings, but amplitude set to zero
	Activa RC	Transfers settings, but amplitude set to zero
	Activa PC	Transfers settings
	Activa SC	Not available
Activa SC	Percept PC	Not available
	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 5 for specific outcomes and considerations.

   Note: 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.
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” on page 8.

Non-rechargeable neurostimulator ONLY: Non-rechargeable neurostimulator battery level is displayed in voltage output and one of three possible states (Table 6).

Table 6. Non-rechargeable battery states

Battery state	Description and required action
OK	The neurostimulator battery is good and no action is needed.
ERI (Elective Replacement Indicator)	**The neurostimulator is nearing the end of its service life and needs to be replaced.** 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.
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 25 percent and is displayed in one of three possible states (Table 7).

Table 7. Rechargeable battery states

Battery state	Description and required action
Percentage (eg, 75%)	The neurostimulator battery is good and no action is needed.
ERI (Elective Replacement Indicator)	**The neurostimulator is nearing the end of its service life and needs to be replaced**. Replace the neurostimulator within 12 months. **Note:** Before replacement, ensure the neurostimulator has provided the updated service life of 15 years. For detailed information on the extended service life, see “Extended service life (Activa RC only)” below.
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.

Extended service life (Activa RC only)

The Activa RC rechargeable neurostimulator will reach end of service at its preset battery life of nine (9) years. However, the Activa RC neurostimulator is capable of providing 15 years of operation after implant. Therefore, the first time you communicate with the Activa RC neurostimulator via the clinician tablet and programmer app, the Activa RC neurostimulator service life will be automatically extended to 15 years after implant.

A confirmation window will appear, indicating that the device service life was extended successfully. In addition, the elective replacement indicator (ERI) date will be updated on the **HOME** screen.

Note: If the tablet and app have not communicated with the Activa RC neurostimulator within nine (9) years after implant, the service

life of that neurostimulator will remain nine years and the end of service (EOS) message will be displayed. At this time, the Activa RC neurostimulator will no longer provide stimulation and a replacement neurostimulator will be needed.

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 use the patient control device for any indication-specific needs.
- How to return unwanted handsets to Medtronic for disposal, to ensure patient privacy is protected.

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 inside 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” on page 31.

You can also view or print the Session Report, which shows the impedance measurements. Refer to “REPORTS” on page 47.

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” on page 32.

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 screening cable to test the impedance of the lead alone.
   - If the impedance value is less than 2,000 Ω (monopolar) or 4,000 Ω (bipolar), then the lead is intact.
   - If the impedance value is greater than 2,000 Ω (monopolar) or 4,000 Ω (bipolar), visually or fluoroscopically inspect the lead for damage.

4. If lead is intact, reconnect the lead to the extension and use a screening cable to test the impedance of the lead and extension together.
   - If the extension impedance value is below 2,000 Ω (monopolar) or below 4,000 Ω (bipolar), the extension is intact.
   - If the extension impedance value exceeds 2,000 Ω (monopolar) or 4,000 Ω (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.

5. Re-connect 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 (monopolar) or below 4,000 Ω (bipolar), the neurostimulator is intact.
- If the neurostimulator impedance value exceeds 2,000 Ω (monopolar) or 4,000 Ω (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 inside 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” on page 31.
- You can also view or print the session report, which shows the impedance measurements. Refer to “REPORTS” on page 47.

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” on page 32.

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 (monopolar configurations)

OR

If electrode impedance values are between 4,000 Ω and 40,000 Ω (bipolar configurations):

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” on page 32.
    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:

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 8), 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 8. Component specific maximum impedance in ohms (Ω)

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

USAGE SCREEN

The **USAGE** screen has two tabs: the **Device Usage** tab and the **Battery Recharge** tab.

HOME > Menu button (☰) > Usage

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.
2. Tap **Usage**.

Device Usage tab

The **Device Usage** tab on the **USAGE** 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 tab

The **Battery Recharge** tab shows the following information for each recharge session over time:

- Recharge duration.
- Recharge coupling.
- Battery level at start and end of recharge.

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 recharge session. The date is displayed along the bottom of the graph.
- The duration of the recharge is listed above each bar.
- Recharge coupling represents the median signal strength from recent recharge sessions.
- If fair or poor strengths are present, discuss recharger positioning with the patient.
- 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 (in 25-percent increments).

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” on page 48.

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

- **Session Report –** contains information specific to a programming session.
- **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 Session Data –** contains a CSV file of session data that can be used for further analysis.
- **Export Session Annotations –** contains a CSV file of session annotations that can be used for further analysis.
- **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 9.

Table 9. Report buttons and options

Button or icon	Definition
	**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.
	**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.
	**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 (ENS or INS), tablet, clinician app, controller, recharger, and communicator.
  - Communicator information is for the most recent communicator to have paired to the tablet.
  - Recharger (if shown) and patient control device information are for the most recent patient control device and recharger 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” on page 47.

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.

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.

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.
- **Caution –** Indicates a caution and that the message should be read and acknowledged.
- **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 10 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 10. 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. – Refer to “Communicator icons in tablet status bar” on page 11 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.

Table 10. Communicator troubleshooting

Problem	Possible Solutions
	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” on page 11 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.

Table 10. Communicator troubleshooting

Problem	Possible Solutions
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 communicator is unresponsive.	Turn off the power for the clinician tablet or the communicator, then turn the power on.
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.

Table 10. Communicator troubleshooting

Problem	Possible Solutions
	– Refer to “Pairing the communicator to the clinician tablet” on page 12. 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 “HIGH-OUTPUT INTERLOCKS OR STIMULATION SETTINGS OUT OF RANGE (OOR)” on page 18.

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 a short in the system.
2. Change the electrodes that are providing stimulation.

Using impedance measurements for troubleshooting

Refer to “ELECTRODE IMPEDANCE TROUBLESHOOTING (INTRAOPERATIVE)” on page 42 for information on intraoperative troubleshooting.

Refer to “ELECTRODE IMPEDANCE TROUBLESHOOTING (POST-IMPLANT)” on page 43 for information on post-implant troubleshooting.

To reset a neurostimulator

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

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 inside back cover of this manual if additional assistance is needed.

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

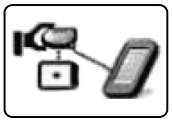
Table 11. Contact Physician error codes on patient control devices

Error code	Explanation
0 to 250	Invalid settings were detected in the patient control device. The patient should remove the patient control device batteries and reinsert them after a few seconds. The error code should disappear. If it reappears, the patient control device may need to be replaced.
528 OOR	Out-of-Range 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. If OOR occurs while using current mode, switch to voltage mode.
570 580 606	Contact Medtronic.
574	No programs or groups were saved by the clinician programmer. The neurostimulator must be reprogrammed.
575 578	Invalid settings were detected in the neurostimulator. The neurostimulator must be reset and valid settings entered.

Table 11. Contact Physician error codes on patient control devices

Error code	Explanation
579 POR	The neurostimulator has undergone a power on reset. No therapy is available until the neurostimulator is reactivated. The patient control device can be used to reactivate the neurostimulator after some PORs (see error code 621). If the patient control device cannot reactivate the neurostimulator, the clinician programmer must be used to reactivate the neurostimulator.
583 586 EOS	The neurostimulator has reached end of service (EOS) and therapy is not available. Replace the neurostimulator.
587 ERI	The rechargeable neurostimulator is within 12 months of its scheduled end of service. The non-rechargeable neurostimulator is within 10 weeks of its scheduled end of service. Please schedule a date to replace the neurostimulator.
601 602 603 604	The patient must come into the clinic. If using an older programmer or patient control device, retry using a newer programmer or patient control device. If the issue persists, contact Medtronic.
621	The neurostimulator has undergone a power on reset, but the patient can resolve this on their own, without coming into the clinic. However, note that eventually this will lead to an error code 579, at which point the patient will need to come into the clinic, and the clinician programmer must be used to reactivate the neurostimulator.

Table 11. Contact Physician error codes on patient control devices

Error code	Explanation
572 574 605	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.
619 620	Review neurostimulator settings with the patient control device to confirm restored function.
810	If the issue persists, contact Medtronic.
378 556 589	The neurostimulator battery was overcharged. The patient must come into the clinic, and the clinician programmer must be used to determine neurostimulator status.
	The external neurostimulator you are trying to communicate with is not configured for use with Activa Therapy. Use the clinician programmer to configure the external neurostimulator for the appropriate therapy.

Patient unable to charge rechargeable neurostimulator (Physician Recharge Mode)

If the patient allows the implanted neurostimulator to overdischarge, telemetry is no longer available from the neurostimulator. The patient will not be able to charge the neurostimulator battery using the charging system.

The patient must return to the clinic, and the physician must charge the neurostimulator battery using the Physician Recharge Mode on the recharger. Typically, the neurostimulator will return to normal charging mode in less than 60 minutes. If it does not, the process

should be repeated. If the neurostimulator cannot be charged, it must be replaced.

To perform a physician recharge

The Information for Prescribers booklet has precautions related to Physician Recharge Mode. Complete the following steps to perform a physician recharge. For further assistance when using Physician Recharge Mode, contact Medtronic using the information on the inside back cover of this manual. In the U.S., call 1-800-707-0933 for Medtronic Technical Services.

Using the Model 37751 Recharger

1. Palpate the patient's skin to determine the best location for the charging antenna, and place the antenna over the neurostimulator.
2. Simultaneously press and hold down the **Start** key and **Audio** key located on the front of the recharger (Figure 9) for 10 seconds. A screen with a 60-minute timer will appear, and charging begins.

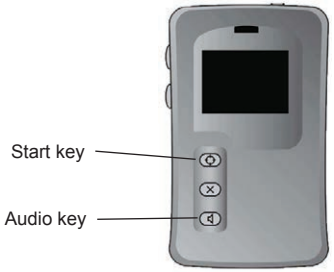


Figure 9. Recharger.

3. Continue charging until the recharger displays a new screen indicating the neurostimulator battery charge level and charging efficiency (Figure 10).

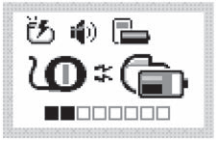


Figure 10. Screen displaying charge level and charge efficiency.

4. Repeat steps 1-3 if the new screen does not appear within 60 minutes.
5. Use the clinician programmer to check settings and to turn stimulation on.

Using the Model WR9200 Recharger

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 implant after the beeping stops. The reset will start after the beeping ends and will take up to 1 minute to complete. The recharger 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 60 minutes if the neurostimulator battery needs to be recovered. Keep the recharger over the implant 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. Check therapy status after performing Physician Recharge and turn on therapy if necessary.

For instructions on performing a normal recharging session using the Model WR9200 recharger, see the manual provided with the recharger.

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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