

Stimulation RC Clinician Programmer Application

A71400

Programming Guide

Neurostimulation systems for pain therapy
Model 977119 Inceptiv™ and Model 977117 Inceptiv™ LT
neurostimulators

Application version 1.0

! USA
Rx only

Medtronic

Explanation of symbols

 ! USA	For USA audiences only
 Manufacturer	
 EC REP	Authorized representative in the European Community
 Importer	

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Information available for the system:

The information for prescribers manual provides information about contraindications, warnings, precautions, adverse events, sterilization, patient selection, individualization of treatment, and component disposal. For customers in Japan, the appropriate package insert provides information about safety, contraindications, warnings, precautions, and adverse events.

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

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

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

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

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

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

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

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Description of the Programming System

Model A71400 Stimulation RC Clinician Programmer Application

The Medtronic Model A71400 Stimulation RC Clinician Programmer Application (app) is intended for use by clinicians in the programming of the following Medtronic neurostimulators:

- Model 977119 Inceptiv™ Implantable Neurostimulator
- Model 977117 Inceptiv™ LT Implantable Neurostimulator

Intended purpose

The clinician programmer application is intended for use by clinicians in the programming of Medtronic neurostimulators for pain therapy.

Other components of the programming system

The clinician programmer app is intended for use with the following components.

Model CT900 Clinician Tablet

The clinician programmer app is installed on the Model CT900 Clinician Tablet with Android™*-based operating system.

Model 8880T2 Communicator

The Model 8880T2 Communicator is a handheld device used in conjunction with the clinician tablet and clinician programmer app to communicate with Medtronic neurostimulators.

Model A901 Communication Manager application

The Model A901 Communication Manager app works with the A71400 Clinician Programming app to manage telemetry communication between the tablet and the neurostimulator. You do not need to open or use the Communication Manager app.

Model A902 Patient Data Service application

The Model A902 Patient Data Service app works with the A71400 Clinician Programming app to store patient and therapy device records that are used when generating a report. You do not need to open or use the Patient Data Service app.

Programmable Settings

The clinician programmer app is used to enter, review, and modify programmable settings in the neurostimulator. These programmable settings define the stimulation therapy delivered to the patient.

Stimulation parameters

Stimulation is delivered in the form of electrical pulses. Stimulation parameters define the attributes of these pulses and can be adjusted to manage patient therapy.

- **Electrode configuration:** Programmed negative (–) polarity, positive (+) polarity, or off.
- **Pulse width:** Duration of each pulse in microseconds (μ s).
- **Rate:** Frequency of pulses in hertz (Hz).
- **Amplitude:** Strength of a pulse in millamps (mA).

Programming styles

The clinician programmer app has three programming styles with differing features for programming stimulation therapy.

- **Legacy:** Basic programming style that provides up to 4 individual programs per group. Refer to page 28 for more information.
- **DTM SCS:** Includes initial values for parameters and optional DTM SCS templates, which can aid in programming Differential Target Multiplexed™ Spinal Cord Stimulation (also known as DTM™ SCS). The clinician then assesses the initial values for parameters and the starting point for electrode configuration and can make adjustments for optimizing pain relief and patient comfort. Refer to page 33 for more information.

- **Neuro Sense:** Includes sensing and control algorithms for Neuro Sense programming, which may be useful for patients who feel uncomfortable stimulation with certain movements or activities. Refer to page 36 for more information.

The programming style determines which programming features are available on the **Program** screen. The programming features may aid the clinician in assigning stimulation parameters with the ultimate goal of optimizing pain relief while maintaining comfortable stimulation.

The Inceptiv neurostimulator supports all three programming styles. The Inceptiv LT neurostimulator supports the Legacy programming style only.

Optional features

Optional features are available for adjusting the stimulation to the patient's needs. Some features are not available for the Inceptiv LT neurostimulator.

- **AdaptiveStim™ Technology:** Adjusts stimulation automatically when the patient changes position.
- **Adjustment:** Allows the patient to increase or decrease amplitude for all programs in the active group at the same time.
- **Cycling:** Cycles stimulation on and off at clinician-determined intervals.
- **DTM SCS templates:** A feature that provides options for electrode starting points that are based on the setup of the spine anatomy view. The clinician then assesses and can make adjustments to the electrode configuration for optimizing pain relief and patient comfort.
- **Electrode Redistribution:** Assigns a lower or a higher percentage of the program amplitude to an individual electrode in a program.

- **Equalize:** Sets program amplitude to zero and reconfigures the active electrodes to provide equal distribution of amplitude.
- **IntelliStim:** A semi-automated feature for selecting electrodes to deliver therapy. IntelliStim is a scanning process in which common combinations of electrodes are scanned across the lead using the selected amplitude.
- **Move:** Sets program amplitude to zero and allows a configured electrode combination to be moved up, down, or across the lead or leads.
- **Patient Limits:** Identifies the stimulation parameters that the patient can adjust and sets the upper limits for those parameters.
- **SoftStart/Stop™ feature:** Slowly increases the amplitude when stimulation is turned on and slowly decreases the amplitude when stimulation is turned off.
- **Spine anatomy view:** A manually adjustable graphic on the **Lead Manipulation** screen. Based on the clinician's interpretation of patient imaging, the clinician adjusts the graphical representation of the leads and electrodes to illustrate the position of the implanted leads relative to the spine. The DTM SCS templates are based on the setup of the spine anatomy view.

Data Security and Network Connectivity

Data security

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

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

Network connectivity

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

- Secure your clinician tablet by disabling network connectivity during any programming session.
- Use a managed, trusted Wi-Fi™* connection when network connectivity is needed.
- Connect the clinician tablet to the network periodically to check for notifications on available updates.

Note: Connecting the clinician tablet to a network that includes other equipment could result in unforeseen risks to patients, operators, or third parties. Changes to your network such as adding, disconnecting,

and upgrading equipment; upgrading or installing software; or changing network configurations could also introduce additional risks. Analyze, evaluate, and control any identified risks.

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

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

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

Installing application updates

Medtronic periodically updates the therapy app and will not install updates without notifying you. Network connectivity is required to update the app. When notified that an app update is available, follow the instructions provided by Medtronic to install the update.

To avoid delays in programming, plan for updates accordingly.

Installing communicator updates

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

Returning the clinician tablet

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

General Warnings and Cautions

If a serious incident related to the app occurs, immediately report the incident to Medtronic and the applicable competent authority.

MRI warning for scan eligibility

 **Warning:** Always program the following component information accurately:

- Neurostimulator and lead model numbers
- Neurostimulator implant location and lead tip location
- Presence of any abandoned leads, extensions, and pocket adaptors

If this information is not up-to-date or is entered incorrectly, MRI scan eligibility data will be inaccurate, and the patient is at risk for one of the following:

- The patient is allowed to have an MRI scan inappropriate for the implanted components, which could cause tissue heating, resulting in tissue damage or serious patient injury.
- The patient is unnecessarily restricted from having an MRI scan.

Refer to the *MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain* instructions for use manual for MRI scan eligibility information, MRI scan conditions, and MRI-specific warnings and cautions for conducting an MRI scan.

Sterile field warning for programming components

 **Warning:** To use the programming components (external and nonsterile) in a sterile field, place a sterile barrier between the patient and the programming components to prevent infection. Do

not sterilize any of the programming components. Sterilization may damage the programming components.

EMI caution for telemetry signal disruption

 **Caution:** Electromagnetic interference (EMI) can disrupt programming and telemetry communication. If EMI interference is suspected, such as from radio frequency identification (RFID) equipment, move away from the likely source of EMI and try again.

Cautions regarding uncomfortable or unexpected stimulation

 **Caution:** Adjust stimulation parameters in small increments above the perception threshold (the parameter values at which the patient first perceives a sensation of stimulation) to prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation) during a programming session.

 **Caution:** Decrease the amplitude to the perception threshold (the amplitude at which the patient first perceives a sensation of stimulation) before changing the pulse width to prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation). After changing the pulse width, slowly increase the amplitude.

Cautions related to clinician programming and possible interactions with other devices

Refer to the *Information for Prescribers* booklet for cautions related to clinician programming and possible interactions with other devices (such as cardiac devices).

Setting up the Programming System

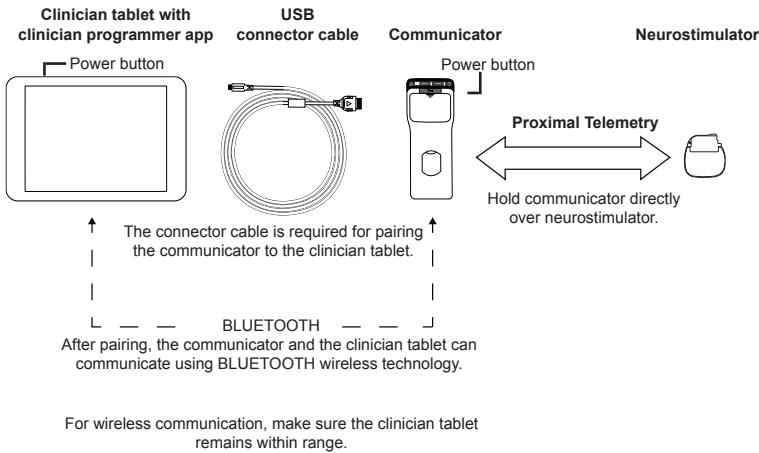


Figure 1. Components of the programming system.

Preparing the clinician tablet

Refer to the *Model CT900 Clinician Tablet* quick start guide for instructions on how to turn on the tablet and to complete initial setup.

Check the battery level of the clinician tablet.

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

Finding and opening the app

1. Navigate to the apps on the clinician tablet.
2. Tap the **Stim RC** app icon to open the app.

Pairing the communicator to the clinician tablet

Refer to the *Model 8880T2 Communicator* technical manual for additional instructions, if needed. Only one communicator can be paired with a clinician tablet at a time.

1. Connect the USB connector cable to the communicator and the clinician tablet.
2. Turn on the communicator (slide the power button down, then release).
3. A message appears on the clinician tablet, 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 message from appearing again.
 - b. Select **OK**.
4. On the initial app screen, tap **CONNECT**. Pairing begins and the communicator displays a green LED light between the tablet icon and the communicator icon.

Once the communicator is paired, you can disconnect the USB connector cable. The communicator and clinician tablet communicate using BLUETOOTH®* wireless technology. For wireless communication, make sure the clinician tablet remains within range.

Note: If you have trouble pairing, either with the USB connector cable or BLUETOOTH, restart the tablet and try again.

Initiating communication with the neurostimulator

1. Hold the communicator directly over the neurostimulator.

Notes:

- The target symbol (\oplus) on the back of the communicator indicates the location of the internal antenna. The target should be facing and centered over the neurostimulator.
- After making the initial connection, you can make future connections at a greater distance for 12 hours following the initial connection, or until the communicator connects to a different neurostimulator.

2. On the **Search for Device** screen, tap **FIND DEVICE**.

Or

Press the communicate button () on the communicator.

3. Select the serial number of the neurostimulator you intend to configure, and tap **CONNECT**.

4. After connecting to the neurostimulator, the **CURRENT DEVICE STATUS** screen will display.

From this screen, you can select workflow options under the **SELECT FLOW** heading. Refer to the "Neurostimulator Workflows" section on page 17 for workflow details.

Notes:

- If you have problems establishing communication, refer to "Communicator and clinician tablet troubleshooting" on page 75.
- Do not leave the clinician tablet unattended during an active programming session.

- When a configured neurostimulator is interrogated, a lead connectivity test is performed to check for impedance issues. The patient may feel a stimulation change during the test.

Overview of the Clinician Programmer App

Using Demo mode

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 is not actual. Neuro Sense data in Demo mode does not update to reflect changes to thresholds, target amplitudes, etc.

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

1. On the initial app screen, tap **DEMO**.
2. Select a device, and tap **CONNECT**.
3. Navigate through a workflow. One workflow at a time can be explored in a Demo session.
4. To exit Demo mode, go to the **Summary** screen, and tap **EXIT WORKFLOW**.

Exiting the workflow will return you to the initial app screen where you can select **DEMO** again and select another device to explore.

Navigating through workflows

The screens typically used during a programming session are grouped into workflows. The workflows vary depending on the device model and device status (new versus configured). The workflows may also vary depending on neurostimulator features.

After you start a workflow, a workflow navigator appears at the top of the screen. For example, the **Followup** workflow for the Inceptiv neurostimulator contains these screens:

Device ► Lead Select ► Tip Location ► Lead Manipulation ► Programs ► Impedance ► AdaptiveStim ► Diaries ► Reports ► Summary

- To move from screen to screen, swipe left or right.
- Alternatively, you can tap on the screen name in the workflow navigator to directly to that screen.
 - If the workflow navigator extends beyond the width of the screen, swipe the workflow navigator left or right to show the screen names that are partially hidden.
- The current screen is underlined and highlighted.
- If input is required in a workflow screen, you will not be able to advance to the next screen until you enter the required input.
 - The app will prompt you for the required input.
 - Orange asterisks indicate required fields.

Using the Side Menu

Screens not in the current workflow can be accessed from the Side Menu. For example, the **Patient Info** screen is in the new device workflow, but not in the **Followup** workflow. To change patient data in a configured device, you need to access the **Patient Info** screen from the Side Menu. To access the Side Menu, tap the **Side Menu** button (≡) in the top-left corner on the action bar.

On-screen help

Help information is available in the clinician programmer app for most workflow screens. View the help information to learn how the app interface works and how to complete tasks on the screen.

- To display help information, tap the **Help** button (ⓘ) in the top-right corner on the action bar.
- Tap the **Help** button (or tap anywhere on the screen) to close the help screen.

Buttons and indicators on the action bar

An action bar appears at the top of all screens in all workflows.

Table 1 describes the buttons and indicators that may appear on the action bar.

Table 1. Buttons and indicators.

Button / Indicator	Description
	Side Menu button: Tap to access screens outside of the workflow.
	Back button: Tap to close a screen you accessed from the Side Menu and return to the previous workflow screen.
DEMO:	Demo mode indicator: Appears in the action bar when in Demo mode.
	Stimulation toggle: Tap to turn stimulation on or off. Green (switch to the right) indicates that stimulation is on. Appears in the action bar when at least one program exists.

Button / Indicator	Description
	AdaptiveStim indicator: Appears in the action bar when AdaptiveStim Technology is enabled.
	MRI Status indicator: Appears in the action bar when stimulation is off and MRI Mode has been activated. The MRI Status indicator does not provide MRI scan eligibility information.
	Help button: Tap to display help information for the current screen. Tap the Help button (or tap anywhere on the screen) to close the help screen.
	Go to Summary screen button: Tap to go directly to the Summary screen. You can exit the workflow from the Summary screen to properly end the programming session.

When the app is placed in the background

When you navigate away from the clinician programmer app while in a programming session, the app is placed in the background and is represented as a floating widget (**Session in Progress**) to remind you that you are still in a session.

- Press and drag the floating widget to move it on the tablet screen.
- Tap on the floating widget to return to the app and resume the session.

Overview of the Communicator

The Model 8880T2 Communicator is a nonsterile component used in conjunction with the clinician tablet and clinician programmer app to communicate with Medtronic neurostimulators.

 **Warning:** To use the communicator in a sterile field, place a sterile barrier between the patient and the communicator to prevent infection. Do not sterilize any of the programming components. Sterilization may damage the programming components.

The communicator is handheld and battery-operated. Communication between the communicator and the 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.

Using the USB connector cable

The following situations require the use of the USB connector cable:

- First-time pairing of any communicator with a clinician tablet.
- Firmware updates to the communicator.
- Environments where multiple devices are using BLUETOOTH wireless technology and thereby creating interference.
- Environments where BLUETOOTH wireless technology is prohibited.

Communicator icons on the tablet status bar

Table 2 describes the icons that appear in the tablet status bar (uppermost row on the tablet screen) indicating the status of the connection between the communicator and the clinician tablet.

Table 2. Communicator icons in the tablet status bar.

Communicator Icon	Description
	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.

Neurostimulator Workflows

When a neurostimulator is interrogated, the clinician programmer app determines if the neurostimulator is new or configured.

A neurostimulator is identified as 'new' if it is in shelf state. A neurostimulator is identified as 'configured' if it has patient data stored in it. Based on the status of the neurostimulator, the clinician programmer app automatically presents the applicable workflow options.

- **Start Usage > Implant Device workflow – go to page 17.**

Use when a new neurostimulator is being configured (programmed) for the first time.

- **Followup workflow – go to page 19.**

Use at followup sessions with the patient.

- **View MRI workflow – go to page 20.**

Use to determine MRI scan eligibility and prepare a patient's neurostimulation system for an MRI scan.

Notes:

- To display on-screen help information, tap the **Help** button (?).
- The screens typically used during a programming session are shown in the workflow navigator. Additional screens not in the current workflow can be accessed from the Side Menu (≡).
- Unsaved information may be lost if the application is improperly terminated during a programming session. To end a session, go to the **Summary** screen, and tap the **EXIT WORKFLOW** button. Ending a session generates a complete session record that is stored in a database on the clinician tablet.

Start Usage > Implant Device workflow

You can initiate communication with the neurostimulator in the package before it is moved into the sterile field. Tasks such as checking the battery status and entering device and patient information can be performed without removing the neurostimulator from the package.

1. On the **CURRENT DEVICE STATUS** screen, confirm that the device information corresponds with the intended neurostimulator.
2. Tap **START USAGE**.
This action takes the neurostimulator out of shelf state and sets the **In Use Date** field to the current date.
3. Under **IMPLANT DEVICE**, tap **START**.
4. Use Table 3 to guide you through the screens and tasks in the workflow.

Table 3. Implant Device workflow.

Screen	Tasks	More information
Device	Check the battery status of the neurostimulator. Select the implant location.	Page 21 Page 21
Patient Info	Enter patient information.	Page 21
Pain Map	Tap the PAINT button, then use your finger to highlight the area on the human figure where the patient feels pain. To remove highlight from an area on the figure, tap the ERASE button, and then tap the highlighted area.	Page 21
Lead Select	Select the implanted leads. Select a lead from the scrollable drop-down list, and then drag and drop it at the appropriate electrode numbers. Tap UPDATE to save the selected lead. Ensure leads are properly connected to the neurostimulator, and then check connectivity by tapping the CHECK CONNECTIVITY button.	Page 22 Page 22
Tip Location	Indicate whether extensions and pocket adaptors are implanted. Indicate whether abandoned leads remain implanted. Select the tip location for each lead.	Page 22
Lead Manipulation	Display the relative position of the implanted leads as viewed from the patient's back. A spine anatomy view can be turned on and used for a graphical representation of the leads relative to the spine.	Page 24
Programs	Create programs in groups. Tap a group to make it active. A highlighted box around a group indicates the group is active. Tap the plus sign to add a program within a group. Program: Refer to the applicable programming style for the programming tasks. Legacy Programming Style DTM SCS Programming Style Neuro Sense Programming Style Energy: Set parameters for SoftStart/Stop and cycling. Estimate recharge interval for the neurostimulator battery with the Check Energy feature. Patient Access: Assign the stimulation parameters that the patient can adjust.	Page 26 Page 28 Page 33 Page 36 Page 47 Page 49
Impedance	Measure electrode impedance. These measurements verify the integrity of lead, extension, and connector pathways. They may provide information about lead problems (such as lead breakage, short circuit, open circuit).	Page 51
Summary	Confirm therapy settings. End the session properly by tapping the EXIT WORKFLOW button.	--

Followup workflow

1. On the **CURRENT DEVICE STATUS** screen, confirm that the patient and device information corresponds with the intended patient and neurostimulator.
2. Under **FOLLOWUP**, tap **START**.
3. Use Table 4 to guide you through the screens and tasks in the workflow.

Table 4. Followup workflow.

Screen	Tasks	More information
Device	Check the battery status of the neurostimulator.	Page 21
Lead Select	Review the information, and make any updates. Updates may delete programmed settings.	Page 22
Tip Location	Review the information, and make any updates.	Page 22
Lead Manipulation	Display the relative position of the implanted leads as viewed from the patient's back. A spine anatomy view can be turned on and used for a graphical representation of the leads relative to the spine.	Page 24
Programs	<p>Review the groups, programs, and settings, and make any updates. Confirm that the active group is the intended group.</p> <p>Program: Refer to the applicable programming style for the programming tasks.</p> <ul style="list-style-type: none">Legacy Programming StyleDTM SCS Programming StyleNeuro Sense Programming Style <p>Energy: Set parameters for SoftStart/Stop and cycling. Estimate recharge interval for the neurostimulator battery with the Check Energy feature.</p> <p>Patient Access: Assign the stimulation parameters that the patient can adjust.</p>	Page 26
Impedance	<p>Measure electrode impedance.</p> <p>These measurements verify the integrity of lead, extension, and connector pathways. They may provide information about lead problems (such as lead breakage, short circuit, open circuit).</p>	Page 51
AdaptiveStim	Configure the settings for AdaptiveStim Technology (Inceptiv neurostimulator only).	Page 57
Diaries	Select a diary to view from the drop-down list. Diaries provide information on therapy usage.	Page 67
Reports	Select a report to view, download, or delete.	Page 69
Summary	<p>Confirm therapy settings.</p> <p>End the session properly by tapping the EXIT WORKFLOW button.</p>	--

View MRI workflow

1. On the **CURRENT DEVICE STATUS** screen, confirm that the patient and device information corresponds with the intended patient and neurostimulator.
2. Tap **VIEW MRI > START**.
3. Use Table 5 to guide you through the screens and tasks in the workflow.

Table 5. View MRI workflow.

Screen	Tasks	More information
Device	Confirm the neurostimulator information and implant location.	Page 55
Patient Info	Confirm the patient information.	Page 55
Lead Select	Confirm the implanted lead information.	Page 55
Tip Location	Confirm the configuration and tip location information.	Page 55
Lead Manipulation	Not applicable to the View MRI workflow.	--
MRI	Review the MRI scan eligibility. Determine whether the patient is eligible for the intended MRI scan. If patient is eligible, turn stimulation off to prepare the patient's neurostimulation system for the scan.	Page 55
Reports	Prepare the MRI Report. The MRI Report contains information intended for MRI clinicians about the MRI scan eligibility of the implanted system.	Page 56
Summary	Confirm that stimulation is off and that MRI status shows the device is ready for an MRI scan. End the session properly by tapping the EXIT WORKFLOW button.	--

Working with Device and Patient Information

Checking battery status of the neurostimulator

The current battery level for the neurostimulator appears on the **Current Device Status**, **Device**, and **Summary** screens. A battery image representing the battery level percentage is displayed on the screen.

At the start of a programming session, if the battery level is below 20%, a message will notify you that the device is running on low battery.

If the battery level is too low to sustain therapy or a programming session, a message will notify you of the battery status and to recharge the device battery now.

Entering implant location

The implant location for implantable neurostimulators is entered on the **Device** screen. The **Device** screen is accessed through the workflow navigator.

- Select the implant location from the scrollable drop-down list.

Note: The implant location impacts the MRI scan eligibility shown on the **MRI** screen.

Entering patient information

Patient information such as patient name and diagnosis is entered on the **Patient Info** screen. The **Patient Info** screen is accessed through the workflow navigator or by tapping **Patient Info** on the Side Menu (≡) when the screen is not part of a workflow.

- Enter the applicable patient information. Orange asterisks indicate the required fields.
- In the **NOTES** section, you can enter notes for the patient that are viewable on the patient control device.

Mapping patient pain

The **Pain Map** screen is used to highlight areas of the body where the patient feels pain. There are two options for updating the patient's pain map: **PAINT** and **ERASE**. Only one can be selected at a time. The **Pain Map** screen is accessed through the workflow navigator or by tapping **Pain Map** on the Side Menu (≡) when the screen is not part of a workflow.

- Select the **PAINT** option, and tap the area on the human figure to highlight where the patient feels pain.
- Use the **ERASE** option to remove highlighting.
- Tap the **ROTATE** button to rotate the human figure from front to back and from back to front.
- Tap **UPDATE**, and swipe left to go to the next screen in the workflow.

Entering lead information

The **Lead Select** screen is used to identify which lead models are implanted, associate the lead electrode numbering to the neurostimulator electrode numbering, and check connectivity of the lead contacts or extension contacts with the neurostimulator contacts.

The **Lead Select** screen is accessed through the workflow navigator.

- To assign a lead, select the lead model from the scrollable drop-down lists. Press and hold, then drag the lead image to the appropriate electrode numbers of the device.
- To delete a lead, tap the lead image, and then tap the **X** that appears.
- To change a lead, you must first delete the current lead, and then assign a new lead.

Notes:

- Make sure the electrode numbering on the screen matches the electrode numbering of the implanted leads. If necessary, you can swap configured leads using the drag-and-drop feature.
- On Medtronic surgical leads, the blue box on the lead arm represents the marker band on the actual lead. For more information about surgical leads, refer to the lead implant manual. The marker band indicates the lead arm for electrodes 0-7.
- The assigned leads impact the MRI scan eligibility shown on the **MRI** screen.

Testing lead connectivity

Once the implanted lead(s) are assigned on the **Lead Select** screen, you can check the connectivity of the lead contacts and/or extension contacts with the neurostimulator contacts. Prior to running the

test, ensure the leads or extensions are properly connected to the neurostimulator.

- Tap the **CHECK CONNECTIVITY** button (☞). (If the button is disabled, tap **UPDATE** on the **Lead Select** screen to save the lead data and enable the button.)
 - Green electrodes indicate that the lead contacts and/or extension contacts have a good connection to the neurostimulator contacts.
 - Red electrodes (with an “X”) indicate a bad connection.
 - If there are red electrodes, gently reconnect the leads or extensions for a better connection to the neurostimulator contacts. Then repeat the connectivity check.

Entering extensions, pocket adaptors, abandoned leads, or tip location information

The **Tip Location** screen is accessed through the workflow navigator.

- Check the **Yes** or **No** checkbox to indicate whether abandoned leads remain implanted.
- Check the **Yes** or **No** checkbox to indicate whether extensions are implanted. If the **No** checkbox is selected for extensions, the **No** checkbox for pocket adaptors is automatically selected.
- Check the **Yes** or **No** checkbox to indicate whether pocket adaptors are implanted.
- Select the tip location for each lead from the scrollable drop-down lists.

Note: The abandoned lead, extension, pocket adaptor, and tip location information impacts the MRI scan eligibility shown on the **MRI** screen.

Adding fluoro images

The fluoro screen is accessed using the **VIEW FLUORO** button on the **Tip Location** screen.

Note: The **VIEW FLUORO** button also appears on the **Lead Manipulation** screen.

- Use the **Add Photo** button to add existing fluoro images saved in the tablet or take a photo of the fluoro image displayed on the monitor. The app can store up to four images.
- Annotate images with the **Text** button. Tap where you want the text to appear on the image and enter the text. Edit existing text by tapping the **Text** button and then tapping the text you want to edit on the screen.
- Tap the **Trash** button (trash icon) to delete an image. If more than one fluoro image exists in the fluoro screen, swipe left or right to select the image you want to delete.

Relative Lead Positioning

The **Lead Manipulation** screen displays the relative position of the implanted leads as viewed from the patient's back. Repositioning the leads on the **Lead Manipulation** screen updates how the leads are displayed on the **Program** screen.

If turned on, the spine anatomy view can be used for a graphical representation of the leads relative to the spine.

- The spine anatomy view is not available for 1x4 or 2x4 leads.
- To turn on the spine anatomy view, the tip location selected on the **Tip Location** screen cannot be sacral or a non-epidural option.
- Also, when two leads are implanted, the combination can only include leads of the same type.

Note: The fluoro screen can be accessed using the **VIEW FLUORO** button on the **Lead Manipulation** screen. Refer to "Adding fluoro images" on page 23 for more information.

Entering the position of the leads with spine anatomy view turned on

The spine anatomy view is a manually adjustable graphic on the **Lead Manipulation** screen, in which the user must manually position the leads relative to the spine to represent the implanted leads.

- If you intend to manually assign electrodes, the spine anatomy view is optional and can be a useful graphical representation of the spine.
- If you intend to use the DTM SCS templates in the DTM SCS programming style, the spine anatomy view must be enabled and manually adjusted.

Complete these steps to set up the spine anatomy view:

1. Tap the **SPINE** toggle to turn on the spine anatomy view.
2. If needed, use the **REFERENCE** drop-down menu to select the vertebra where the top lead tip is located (default reference vertebra is T8).
3. First, align the top electrodes. In the spine anatomy view, move the leads so the top electrodes are at the correct spine location.
 - To move a lead, press and hold the lead, then drag the lead up or down.
 - To swap the position of the leads (for example, to switch the position of lead #2 with lead #1), press and hold the lead, then drag the lead to the location of the other lead.

Notes:

- Use a fluoro image or other diagnostic image for reference when aligning the electrodes to the spine anatomy.
 - Lead position cannot be adjusted toward the spine midline. The position of the leads in relation to the spine midline may not match the fluoro image.
4. Second, align the bottom electrodes. Use the spine size controls to adjust the overall spine size until the bottom electrodes are at the correct spine location.
 - Tap the **LARGER** button or **SMALLER** button to make the overall spine size larger or smaller, respectively.

Note: Changing the overall spine size does not change the size of the leads overlayed on the spine anatomy view.

5. If needed, use the advanced spacing controls to change the size of an individual vertebra or disc. These controls may be useful when a patient has a collapsed disc or crushed vertebra.

- Tap the **ADVANCED SPACING** toggle to turn on the controls.
- Tap the spacing controls ( ) to change the size of an individual vertebra or disc. The controls on the left adjust the vertebrae and the controls on the right adjust the discs.
- If needed, tap **RESET** to return all vertebrae and discs back to the original height.

Note: The **ADVANCED SPACING** toggle must be turned off if you want to move the leads within the spine anatomy view.

6. When all changes are made, tap **UPDATE** to save the changes.

Entering the position of the leads with spine anatomy view turned off

1. Tap the **SPINE** toggle to turn off the spine anatomy view, if necessary.
2. Move the leads to represent the relative position of the implanted leads as viewed from the patient's back.
 - To move a lead, press and hold the lead, then drag the lead up or down.
 - To swap the position of the leads (for example, to switch the position of lead #2 with lead #1), press and hold the lead, then drag the lead to the location of the other lead.

Working with Groups and Programs

Programs screen

The **Programs** screen is used to create, copy, move, and delete programs within groups and to define the active group. The **Programs** screen is accessed through the workflow navigator.

- Only one group can be active at a time. A highlighted box around a group indicates the active group.
- To make another group active, tap that group name.
- To create a new program, tap the add symbol (+) on the desired program. This will launch the **Program** screen, where you can assign the program settings.
- To view the program settings for an existing program, first make the group active, and then tap the program to view the **Program** screen.
- To view the Neuro Sense settings for a Neuro Sense group, first make the group active, and then tap the Neuro Sense group summary.
- To copy or move a program, press and hold, then drag that program to the intended location, and then select **MOVE** or **COPY** from the message that appears.
- To delete a program, press and hold, then drag that program to the **Trash** icon (☒).
- To turn on all programs in a Legacy or DTM SCS group, first make the group active, then tap the group name and confirm the pop-up message (applicable when one or more programs are off).

Notes:

- The AdaptiveStim indicator (⌚) appears next to a group name if AdaptiveStim Technology is enabled for the group.
- The Perception Threshold icon (⚡) appears in a DTM SCS program if the amplitude at which the patient perceived a sensation of stimulation was identified during programming.
- An orange exclamation mark (!) appears next to a program amplitude if the amplitude is at 0.0 mA.
- The icon and name of the programming style appears next to the group name on the **Programs** screen.
 - **Legacy:** Refer to "Legacy Programming Style" on page 28.
 - ◆ **DTM SCS:** Refer to "DTM™ SCS Programming Style" on page 33.
 - ▲ **Neuro Sense:** Refer to "Neuro Sense Programming Style" on page 36.

The programming style for a group is selected on the **Program** screen. The Inceptiv neurostimulator supports all three programming styles. The Inceptiv LT neurostimulator supports the Legacy programming style only.

Program screen

The **Program** screen is used to assign, review, and change program settings for programs in the active group. The **Program** screen is accessed by tapping a program on the **Programs** screen.

- A line is shown under the program name that is currently displayed on the **Program** screen.
- To move from program to program within the active group, swipe left or right on the screen. Alternatively, you can tap a program name.

- For the Inceptiv neurostimulator, use the drop-down menu in the top-left corner to select the programming style. The programming style determines which programming features are available on the **Program** screen.
- From the **Program** screen, you can access these additional screens.
 - Energy:** Refer to "Customizing SoftStart/Stop™ and Cycling Features" on page 47. Refer to "Estimating Recharge Interval" on page 48.
 - Patient Access:** Refer to "Enabling Patient Access" on page 49.

Turning stimulation on or off

The **Stimulation** toggle is found on the action bar at the top-right corner of the screen. The toggle is available when at least one program exists. When no programs exist, the area in the action bar reads "Stimulation Not Setup".

- Tap the **Stimulation** toggle to turn stimulation on () or off () at any time.

Turning individual programs on or off

The **ACTIVATE** toggle is found on the **Program** screen. It is available with the Legacy and DTM SCS programming styles.

- Tap the **ACTIVATE** toggle to turn an individual program on () or off ().

Turning a program off can be helpful in a programming session, for example, when you are trying to determine which program is more effective in delivering therapy.

Interlocks

Certain combinations of pulse width, rate, and number of programs may not be allowed by the clinician programmer app. Interlocks may prevent certain pulse width and rate values from being available for programming. To program a parameter value outside of the interlock limit, try reducing the other parameter value or reducing the number of programs.

Stimulation below programmed amplitude

If the neurostimulator is unable to deliver the amplitude value in combination with the values set for the pulse width and rate, an alert will notify you that stimulation output is below the programmed amplitude. Refer to "Stimulation below programmed amplitude message" in the Troubleshooting section on page 74.

Legacy Programming Style

The Inceptiv neurostimulator and the Inceptiv LT neurostimulator support the Legacy programming style.

With the Legacy programming style, a group can have up to four programs. A program is a specific combination of pulse width, rate, and amplitude settings acting on a specific electrode configuration. The program defines the stimulation pulses that will be delivered for therapy.

When using more than one program, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program, and so on. Pulses from different programs are never delivered simultaneously. Each group and its associated programs can be used to provide therapy for specific areas of coverage or specific patient activities.

Pulse width, amplitude, and electrode configuration are assigned at the program level: that is, each program within a group can have different values. Rate is assigned at the group level, and the rate of each program within a group can be set as a fraction of the group rate.

Assigning electrode configuration

Electrode configuration for the leads is assigned on the **Program** screen.

Electrode configuration must include at least one negative (–) and one positive (+) electrode. You cannot set amplitude for the program until you have assigned at least one negative (–) and one positive (+) electrode to the lead.

- Tap an electrode to change its polarity to negative (–), positive (+), or off. Tap **Update** when finished.
 - A gray electrode signifies that the electrode is unavailable for programming.

- To delete an electrode, press and hold, then drag that electrode to the **Trash** icon (trash).
- To delete all assigned electrodes, tap the **Select All** button (**±**), and then tap the **Trash** icon (trash).
- To move all electrodes at once, tap the **Select All** button (**±**), and then press and drag the electrodes to a new location on a lead. This action will set the amplitude to 0.0 mA.
- To move an individual electrode, you must first delete that electrode and then assign a new electrode.
- To turn the spine anatomy view on and off, tap the **Spine** icon (square).

Note: Adding or deleting an electrode after the amplitude is assigned will reset the amplitude to 0.0 mA for the affected program.

Assigning amplitude, pulse width, and rate

Amplitude, pulse width, and rate are assigned on the **Program** screen.

During a programming session, the selected values for amplitude, pulse width, and rate are automatically programmed into the neurostimulator. Once amplitude is set and stimulation is turned on, the neurostimulator changes stimulation to the new setting every time a stimulation parameter is changed.

To assign amplitude

Amplitude is the strength of the pulse in millamps (mA). The electrode configuration for the leads must be assigned before you can set amplitude.

1. In the **Program** screen, tap **AMPLITUDE** to access the amplitude control.

2. Select the amplitude using any of these controls:
 - Scrollable drop-down list.
 - Dial (press and drag the dot on the dial).
 - Back arrows (to decrease and forward arrows () to increase).

Note: Amplitude increases in increments. When amplitude is decreased, amplitude decreases immediately to the new value.

3. Use these buttons, as needed:
 - Tap the **Stop** button (to stop stimulation from increasing to the new value.
 - Tap the **Jump** button () to jump to the new value without incremental increases.
 - Tap the **Amplitude to zero** button () to immediately set amplitude to 0.0 mA.
4. Tap **CLOSE** to close the control.

To assign pulse width

Pulse width is the duration of the pulses in microseconds (μ s).

1. In the **Program** screen, tap **PULSE WIDTH** to access the pulse width control.
2. Select the pulse width using any of these controls:
 - Scrollable drop-down list.
 - Dial (press and drag the dot on the dial).
 - Back arrows (to decrease and forward arrows () to increase.

3. If stimulation is on, the **Stop** and **Jump** buttons become available when the pulse width is increased. Use these buttons, as needed.
 - Tap the **Stop** button () to stop stimulation from increasing to the new value.
 - Tap the **Jump** button () to jump to the new value without incremental increases.
4. Tap **CLOSE** to close the control.

To assign program rate and group rate

Rate is the frequency of pulses per second, in hertz (Hz). The group rate is the initial rate for each program in that group. A program rate is a fractioned value of the group rate.

Note: If a program has more than 8 electrodes, the group rate will be limited to a maximum value of 50 Hz.

To set a group rate

1. In the **Program** screen, tap **PROGRAM RATE** to access the rate control.
2. Select the group rate using any of these controls:
 - Scrollable drop-down list.
 - Dial (press and drag the dot on the dial).
 - Back arrows (to decrease and forward arrows () to increase.

To set a program rate

A program rate is a fractioned value of the group rate.

The rate ratios available: 1/1, 1/2, 1/3, 1/4, and so on, up to 1/20.

1. If you need to set a program rate, tap the pop-up scrollable list next to **PROGRAM RATE** in the rate control.

- Select a program rate. This rate will only be applied to the selected program.

Program rate example:

- The group rate is set at 100 Hz.
 - 1/2: 50 Hz** is selected as the program rate for that program in the group.
 - This program will now deliver pulses at 50 pulses per second. Meanwhile, the other programs set with the group rate will still deliver 100 pulses per second.
- Tap **CLOSE** to close the control.
 - Reassess limits assigned in the **Patient Access** screen after modifying stimulation parameters. Refer to "Limits" on page 49.

To use electrode redistribution (to assign percentage of amplitude for individual electrodes)

In most programming sessions, the value selected for the amplitude is distributed evenly among the assigned electrodes. Use the electrode redistribution feature when you want to assign a lower or a higher percentage of the amplitude to an individual electrode in the program.

Note: This feature is not available with the Inceptiv LT neurostimulator.

On the **Program** screen, the distribution of the amplitude among the electrodes is shown as percentages for the positive (+) electrodes and as a value for the negative (-) electrodes.

Note: The **Device Electrode Redistribution** feature must be activated before you can use the feature. The feature only needs to be activated once. It remains active across programming sessions.

- To activate the **Device Electrode Redistribution** feature:
 - Tap the **Display All** (CRT) button in the **Program** screen. The **Display All** screen can only be accessed from an active program with at least one electrode pair.
 - In the **Display All** screen, check the status of the **DEVICE ELECTRODE REDISTRIBUTION** toggle. If the toggle is green and the switch is to the right () , the feature is activated. If the toggle is blue and the switch is to the left, tap the toggle to activate the feature.
 - Tap the **CLOSE** button to return to the **Program** screen.

- In the **Program** screen, tap the electrode you intend to adjust.

Notes:

- To maintain the overall balance of energy between the polarities, the electrodes that will be impacted by the redistribution will have the same polarity as the electrode that you selected to adjust.
- Electrode redistribution will automatically rebalance the delivered stimulation amplitudes. After making adjustments, review the electrode contribution percentages.

- Select the percentage of the amplitude that you want to assign to the electrode.

Note: Electrode amplitude increases in increments.

- Repeat if you want to adjust another electrode.

- Tap **CLOSE** to close the control.

To equalize amplitude across electrodes

Use the **Equalize** feature to evenly distribute amplitude across the assigned electrodes. You can equalize amplitude for a single program or for all programs with unequal distribution.

Note: This feature is not available with the Inceptiv LT neurostimulator.

To equalize a single program

1. In the **Program** screen, tap the **Equalize** (均衡) button.
2. Tap **YES** in the confirmation pop-up to proceed.
3. Use the **AMPLITUDE** control to select an amplitude.

To equalize all programs with unequal distribution

1. In the **Program** screen, tap the **Display All** (显示所有) button. The **Display All** screen can only be accessed from an active program with at least one electrode pair.
2. In the **Display All** screen, tap the **DEVICE ELECTRODE REDISTRIBUTION** toggle.
3. Tap **DISABLE** in the confirmation pop-up.

This action equalizes amplitude across all programs with unequal distribution and reduces the amplitude to zero for those programs. It also disables the electrode redistribution and IntelliStim features.

4. Tap the **CLOSE** button to return to the **Program** screen.

To use IntelliStim

IntelliStim is a scanning process in which common combinations of electrodes are scanned across the lead using the selected amplitude. IntelliStim can help find which electrodes to select to deliver therapy.

Note: This feature is not available with the Inceptiv LT neurostimulator.

When IntelliStim begins, the lead is automatically populated with a negative (–) and positive (+) electrode pair:

- Electrode number 0 is assigned a negative (–) polarity.
- Electrode number 1 is assigned a positive (+) polarity.

You can either start the scanning process from the 0 and 1 electrodes, or you can move the negative and positive electrode pair to another position on the lead and start the scanning process from there.

To use IntelliStim, you must first activate the **Device Electrode Redistribution** feature. The feature only needs to be activated once. It remains active across programming sessions.

1. To activate the **Device Electrode Redistribution** feature:
 - a. Tap the **Display All** (显示所有) button in the **Program** screen. The **Display All** screen can only be accessed from an active program with at least one electrode pair.
 - b. In the **Display All** screen, check the status of the **DEVICE ELECTRODE REDISTRIBUTION** toggle. If the toggle is green and the switch is to the right (右侧), the feature is activated. If the toggle is blue and the switch is to the left, tap the toggle to activate the feature.
 - c. Tap the **CLOSE** button to return to the **Program** screen.
2. In the **Program** screen, tap the **INTELLISTIM** button (智能扫描) and follow the on-screen instructions.
3. Position the electrode pair on the lead where you want to start the scanning process.
 - Tap the **Forward** button (前进) to advance the electrode pair down the lead.

- Tap the **Back** button (◀) to advance the electrode pair up the lead.
 - Tap the **Jump Forward** button (▶) to move the electrode pair to the top of the lead or electrode column (if a surgical lead) on the right.
 - Tap the **Jump Back** button (◀) to move the electrode pair to the top of the lead or electrode column (if a surgical lead) on the left.
 - Or move the electrode pair directly to another location on the lead by tapping a target electrode on the lead. (This option becomes unavailable once the **Play** button is pressed for the first time.)
4. Use the **Amplitude** control to set the amplitude.
 5. Tap the **Play** button (▶) and **Pause** button (⏸) to start and pause the scanning process.
 - The button marked **X2** shows the default speed. Tap the button once to reduce speed (the button will now be marked **X1**). Tap the button again to change the speed back to **X2**.
 6. Ask the patient to provide their feedback during the scanning process to assess which electrodes to select to deliver therapy.
 7. Tap **DONE** if you find an effective electrode combination.
 8. If desired, use IntelliStim to create another program in the same group for the other lead or other electrode column (if programming a surgical lead).

DTM™ SCS Programming Style

Only the Medtronic Inceptiv Model 977119 neurostimulator is compatible with the DTM™ SCS programming style.

Differential Target Multiplexed™ SCS (DTM SCS) provides programs with two different rates (low rate for Base and high rate for Prime) and pulse widths.

The DTM SCS programming style displays the Base and Prime programs with starting values for the initial low and high rates and pulse widths, which are adjusted manually by the clinician when optimizing for pain relief and patient comfort.

The DTM SCS programming style also includes DTM SCS templates (an optional feature) that provide electrode starting points for the clinician to assess. The clinician can make adjustments for optimizing pain relief and patient comfort.

Note: DTM SCS can also be programmed manually using the "Legacy Programming Style" on page 28.

Entering the position of the leads relative to spine anatomy

Before you can use the DTM SCS templates, the spine anatomy view must be turned on and the graphical representation of the leads must be positioned relative to the spine anatomy on the **Lead Manipulation** screen. Refer to "Entering the position of the leads with spine anatomy view turned on" on page 24.

Assigning electrodes using DTM™ SCS templates

DTM SCS templates display three options for electrode starting points for the Base and Prime programs.

[!USA] **Note:** The DTM SCS templates were not evaluated in the DTM randomized controlled trial (RCT) described in the clinical summary manual. Therefore, the electrode configurations recommended by the DTM templates were not determined to be more effective at providing pain relief than any other electrode configurations in the DTM RCT study.

- The three optional templates (DTM Upper, DTM Lower, and DTM Middle) provide electrode starting points to assess the patient's response to stimulation at different electrode locations. These templates can be assigned to different groups; refer to "Working with multiple DTM™ SCS groups" on page 35.
- The clinician can manually adjust the electrode configuration on the Base and Prime program screens to optimize the patient's pain relief while maintaining comfortable stimulation.

Note: DTM SCS templates are not available for 1x4 or 2x4 leads.

1. On the **Programs** screen, tap a group name to make it active; then tap a program.
2. On the **Program** screen, select **DTM SCS** from the drop-down menu in the top-left corner.
3. Tap the **TEMPLATES** button.
4. On the **DTM SCS TEMPLATES** screen, select the applicable template(s) with the desired electrode configuration. For each selected template, a group with a Base program and a Prime program will be created.
 - a. Tap the checkbox next to each template that you want to use.
 - b. Tap **UPDATE**.

Note: If you choose to manually assign electrodes or need to move or delete electrodes, refer to "Assigning electrode

configuration" on page 28.

5. (Optional) If you want to use the electrode redistribution feature, refer to "To use electrode redistribution (to assign percentage of amplitude for individual electrodes)" on page 30.

Assigning amplitude

With DTM SCS programming, the stimulation amplitude for each program is based on the amplitude at which the patient perceives a sensation of stimulation, which is known as the perception threshold (PT). After the PT amplitude is recorded, a table appears showing amplitude values at various percentages of the PT amplitude to aid the clinician in selecting the stimulation amplitude.

Note: The starting amplitude for all programs is always zero. Adjust the amplitude to optimize pain relief while maintaining comfortable stimulation.

To assign amplitude for the Base program

1. On the **Program** screen, tap the **Base Program (1)** tab.
2. Tap the **AMPLITUDE** control, and use the available options to determine the perception threshold. Have the patient inform you when the stimulation is perceived. If ramping is being used, tap the **Stop** button () when stimulation is perceived.
3. Once the perception threshold is determined, tap the **PT** button () to record the PT amplitude.
After the PT amplitude is recorded, a table appears showing amplitude values at various percentages of the PT amplitude.
4. Set the amplitude to a comfortable level for the patient.

Note: If pain relief and patient comfort cannot be achieved, consider manually adjusting parameters or the electrode configuration (or both).

To assign amplitude for the Prime program

1. On the **Program** screen, tap the **Prime Program (2, 3, 4)** tab.
2. Tap the **AMPLITUDE** control, and use the available options to determine the perception threshold. Have the patient inform you when the stimulation is perceived. If ramping is being used, tap the **Stop** button () when stimulation is perceived.
3. Once the perception threshold is determined, tap the **PT** button () to record the PT amplitude.
After the PT amplitude is recorded, a table appears showing amplitude values at various percentages of the PT amplitude.
4. Set the amplitude to a comfortable level for the patient.

Note: If pain relief and patient comfort cannot be achieved, consider manually adjusting parameters or the electrode configuration (or both).

Assigning pulse width and rate

The initial pulse widths and rates are starting values for the clinician to assess. The clinician can make adjustments for optimizing pain relief and patient comfort.

In the DTM SCS programming style, the Base Program (1) starting values for the rate and pulse width are 50 Hz and 200 μ s. In the DTM SCS programming style, the Prime Program (2, 3, 4) starting values for the rate and pulse width are 300 Hz and 170 μ s.

I USA **Note:** These values were not determined to be more effective at providing pain relief than any other starting values in the DTM RCT

study described in the clinical summary manual. Starting values for DTM programming were not specified in the clinical study.

1. To make changes to pulse width or rate:

- Tap the **PULSE WIDTH** control, and use the available options to modify the pulse width value.
- Tap the **PROGRAM RATE** control, and use the available options to modify the rate value.

Working with multiple DTM™ SCS groups

If more than one group was created using DTM SCS templates, you will need to assess the Base program and the Prime program in each created group. Adjust the stimulation parameters and electrode configurations to optimize pain relief and patient comfort.

The starting amplitude for all programs is always zero. To assess each group, go to the **Programs** screen, tap the name for the group to make that group active, and then tap the Base or Prime program. On the **Program** screen, assign the amplitudes for the Base and Prime programs. Adjust amplitude, pulse width, rate, and the electrode configuration as needed to optimize pain relief and patient comfort. Repeat the steps for all of the created groups.

Neuro Sense Programming Style

Only the Medtronic Inceptiv Model 977119 neurostimulator is compatible with Neuro Sense programming.

The Inceptiv neurostimulator supports the Neuro Sense programming style when it is implanted with 1x8 compact lead types, including the Medtronic Vectris™ SureScan™ MRI 1x8 Compact Lead Models 977A260, 977A275, and 977A290.

Notes:

- Leads with similar electrode spacing, geometries, and impedances are expected to allow for sensing; however, the performance of the Neuro Sense programming style on other lead models has not been established.
- The Neuro Sense feature has not been demonstrated to be effective for Medtronic Specify™ SureScan™ MRI 5-6-5 Lead Models 977C165 and 977C190.

With the Neuro Sense programming style, a program can be configured with stimulation electrodes at one end of the lead and sensing electrodes at the other end of the lead. In this configuration, the system can deliver stimulation and also sense the body's neurological response to the stimulation as an evoked compound action potential (ECAP).

An ECAP is a physiological response by the body when a group of nerve fibers in the spinal cord is activated by an electrical stimulus. This body signal is the sum of all signals from the activated nerve fibers. As more fibers are activated due to an increase in stimulation, the body signal size gets larger and can be measured.

Neuro Sense programming may be useful for patients who feel uncomfortable stimulation with certain movements or activities. Patients may experience a momentary intense sensation (some describe it as a tingling, jolting, or shocking sensation) when the

spinal cord receives a greater amount of stimulation than desired. An increase in stimulation can occur when the distance between the spinal cord and the implanted leads decreases. This change in distance may be caused by events such as sneezing or coughing or positional changes such as bending or stretching.

With the capability to sense and measure body signals, an algorithm can be configured to automatically lower stimulation amplitude if the body signal size goes above an upper threshold and then return stimulation amplitude toward the programmed amplitude when the body signal size goes below a lower threshold. The algorithm can respond to changes in stimulation within milliseconds and make amplitude adjustments that compensate for patient movement and activity.

Terminology

Neuro Sense programming – Programming that enables the Inceptiv neurostimulator to deliver stimulation and also sense the body's neurological response to the stimulation as an evoked compound action potential (ECAP).

Body signal – The measurable neurological signal from the body when nerve fibers in the spinal cord are activated by stimulation.

Signal size – The size of a body signal measured from the low point to the high point of the signal waveform and recorded in microvolts (μV).

Stimulation electrodes – The electrodes on the lead that deliver the stimulation pulses used to elicit body signals.

Sensing electrodes – The electrodes on the lead that sense the body signals.

Program 1 – The program that defines the stimulation pulses used to elicit body signals. The program is configured with stimulation electrodes at one end of the lead and sensing electrodes at the other end of the lead.

Program 2 – An optional program that can be used in conjunction with Program 1 to deliver additional therapy.

Reaction threshold – The upper threshold for body signal size. When the algorithm is active and body signal size goes above this value, the system will decrease stimulation amplitude.

Recovery threshold – The lower threshold for body signal size. When the algorithm is active and body signal size goes below this value, the system will increase stimulation amplitude toward the target amplitude.

Target amplitude – The maximum stimulation amplitude that the system will deliver for each program when the algorithm is active.

Sense Only/Active toggle – The control used to activate and deactivate the algorithm. When the toggle is set to Active, the system senses and measures body signals and makes amplitude adjustments based on those signals. When the toggle is set to Sense Only, the system senses and measures body signals, but no amplitude adjustments are made.

Graphs

The following example graphs show the type of data used with Neuro Sense programming.

Figure 2 shows an example plot of body signal size measurements recorded over time. The graph is used to identify if a body signal of sufficient size is recorded when a patient performs a movement or activity that may cause a momentary intense sensation (such as a back arch or cough). If there is a signal of usable size, the system selects the largest body signal by default and marks the signal on the graph. The system automatically calculates the initial values for the Reaction and Recovery thresholds from the signal information.

Figure 3 shows an example waveform for a body signal. The graph is used to review the quality of the signal. There should be a pronounced low point and high point in the curve for it to be considered a good signal. This graph is also used to check that the low point detection window and high point detection window are positioned correctly. The system automatically assigns the detection windows based on the Program 1 electrode configuration. The detection windows define the period of time when the system looks for a low point value and a high point value in the curve. These values are used to calculate the body signal size. In Figure 3, the calculated body signal size is 39.9 μ V. Adjustments to the detection windows are typically not needed but can be made by dragging the window handles.

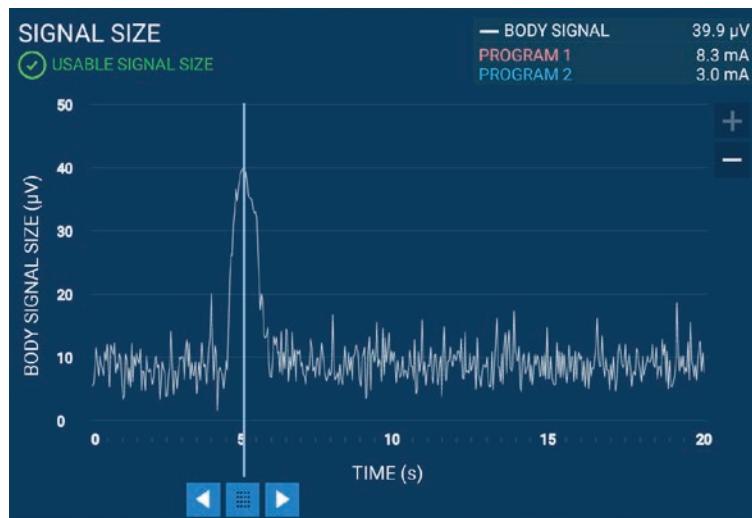


Figure 2. Example of SIGNAL SIZE graph.

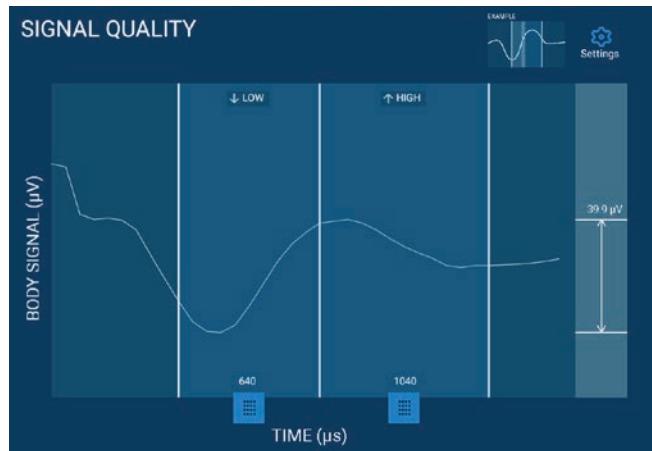


Figure 3. Example of SIGNAL QUALITY graph.

Figure 4 shows the type of data captured when Neuro Sense programming is in Active mode and the patient is performing various movements and activities.

The top graph shows body signal size measurements recorded over time. The yellow line identifies the Reaction threshold (15 µV in this example). The magenta line identifies the Recovery threshold (10 µV in this example).

The bottom graph shows the corresponding changes in stimulation amplitude made by the system. The solid pink line shows the amplitude changes to Program 1, and the solid blue line shows the amplitude changes to Program 2. The dotted lines show the target amplitudes for Program 1 (8.3 mA) and Program 2 (3.0 mA).

With Neuro Sense programming in Active mode, whenever the body signal size goes above the Reaction threshold, the system decreases the stimulation amplitude for both programs. Whenever the body signal size goes below the Recovery threshold, the system increases the stimulation amplitude for both programs but only until the target amplitude is reached. Whenever the body signal size is between the Reaction threshold and Recovery threshold, the system maintains the present stimulation amplitude for each program.

The thresholds can be adjusted in real time based on patient feedback. The target amplitudes can also be adjusted, but Neuro Sense programming must be temporarily placed into Sense Only mode to make adjustments to target amplitudes.

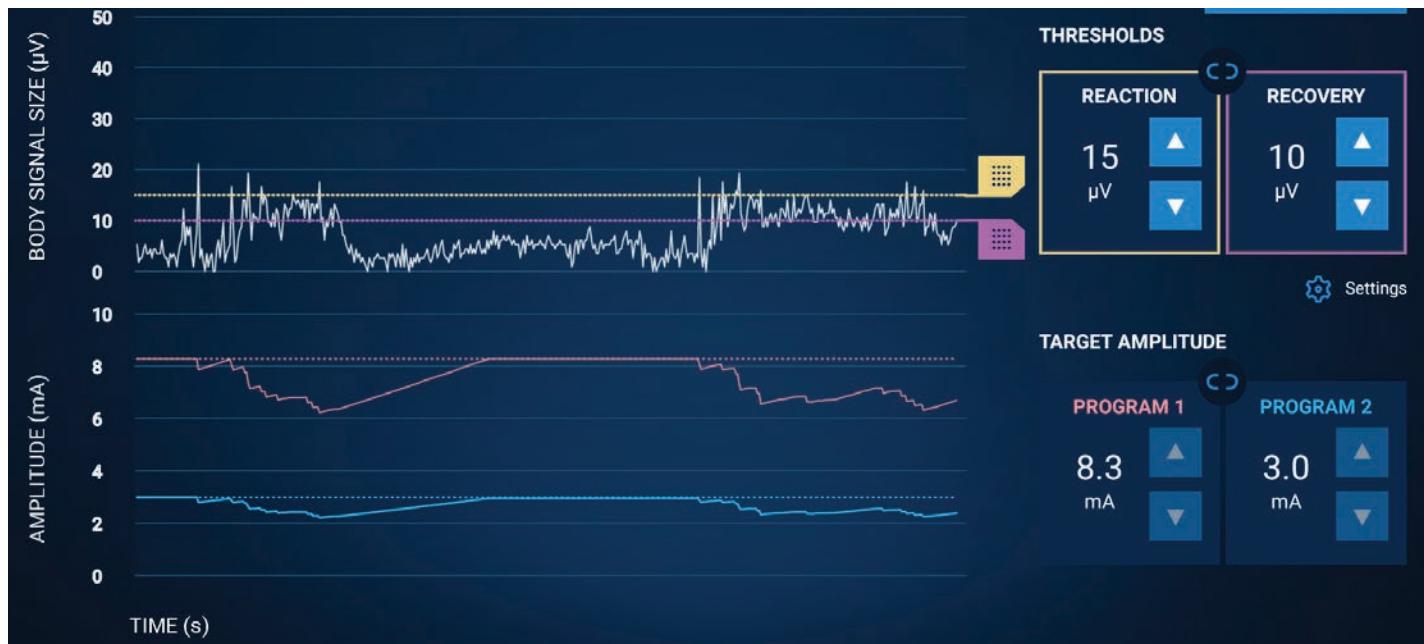


Figure 4. Example of data captured when Neuro Sense programming is in Active mode.

Creating programs

Program 1 defines the stimulation pulses used to elicit body signals. Program 2 is an optional program that can be used in conjunction with Program 1 to deliver additional therapy.

Note: Prior to creating programs, consider running an impedance check to determine if any electrodes should be avoided. Refer to "Checking System Performance" on page 51.

Programming constraints

The following programming constraints apply to Neuro Sense programming.

Note: The Neuro Sense feature has not been demonstrated to be effective for Medtronic Specify™ SureScan™ MRI 5-6-5 Lead Models 977C165 and 977C190.

- The stimulation electrodes and the sensing electrodes in Program 1 must be placed at opposite ends of the lead.
- There must be at least two electrodes configured for sensing in Program 1.
- A positive electrode is required between the negative electrode and the closest sensing electrode in Program 1.
- The sensing electrodes in Program 1 cannot be used as stimulation electrodes in Program 2.
- Program 2 is limited to a maximum of eight electrodes.
- When using a 1x8 lead, the stimulation electrodes in Program 1 can only be in a bipolar (-, +) configuration or a configuration with a guarded cathode (+, -, +, -).
- When using a 5-6-5 lead, the stimulation electrodes in Program 1 can only be in a bipolar (-, +) configuration. The Program 1 stimulation and sensing electrodes can only be configured on the midline array (electrodes 5, 6, 9, and 10).

- When using a 5-6-5 lead, the electrodes next to the sensing electrodes cannot be used for stimulation.
- The stimulation parameters for Program 1 are limited as follows:
 - The rate is fixed at 50 Hz.
 - The pulse width is limited to 120, 150, or 200 µs.
 - The amplitude is limited to 10.0 mA or less.
- The rate for Program 2 is limited to 50-1200 Hz. To assign a rate of more than 50 Hz, you must first do the following:
 - Configure Program 2 so that it only uses two electrodes.
 - Only use electrodes on the same lead as Program 1 when two leads are implanted.
 - Set the Program 2 amplitude to 10.0 mA or less.

Using the Targets feature in programs

If you want to use a standardized programming protocol (eg, DTM SCS) in a program, you can make a selection from the **Targets** drop-down menu on the **Program** screen and get on-screen guidance to aid in electrode placement. In the spine anatomy view, a line will appear showing the suggested location for the negative electrode based on the programming protocol.

Before you can use the Targets feature, the spine anatomy view must be turned on and the leads must be positioned relative to the spine anatomy on the **Lead Manipulation** screen. Refer to "Entering the position of the leads with spine anatomy view turned on" on page 24.

To create Program 1

1. On the **Programs** screen, tap a group name to make it active; then tap **Program 1**.

- On the **Program** screen, select **Neuro Sense** from the drop-down menu in the top-left corner.
- Drag either the stimulation region or the sensing region onto the lead (acceptable areas are marked by dotted lines).

Note: You only need to drag one of the regions onto the lead. The other region is automatically assigned at the opposite end of the lead.

- The system automatically assigns a bipolar configuration to the stimulation electrodes.
 - If the bipolar configuration is acceptable, tap **Update**.
 - If the bipolar configuration is not acceptable, tap an electrode to change its polarity to negative (-), positive (+), or off. Tap **Update** when finished.
 - If you need to re-assign the sensing and stimulation electrodes, first delete all assigned electrodes by tapping the **Select All** button () and then tapping the **Trash** icon ().

Note: When an acceptable electrode configuration is assigned, the orange exclamation mark () changes to a green check mark ().

- Next, set the stimulation parameters to achieve the desired therapy.
 - Tap the **PULSE WIDTH** control, and use the available options to modify the pulse width value, if desired.
 - Tap the **AMPLITUDE** control, and use the available options to set the amplitude value.
- (Optional) The perception threshold (PT) and the discomfort threshold (DT) may be recorded for future reference. The perception threshold is the amplitude at which the patient perceives the sensation of stimulation. The discomfort

threshold is the amplitude at which the patient feels that the stimulation is uncomfortable.

- PT amplitude: Have the patient inform you when the stimulation is perceived. If ramping is being used, tap the **Stop** button () when stimulation is perceived. Once the perception threshold is determined, tap the **PT** button () to record the PT amplitude.
- DT amplitude: Have the patient inform you when stimulation feels uncomfortable. If ramping is being used, tap the **Stop** button () when stimulation feels uncomfortable. Once the discomfort threshold is determined, tap the **DT** button () to record the DT amplitude.
- Set the amplitude to a comfortable level for the patient.

To create Program 2 (optional program)

- On the **Program** screen, tap the **Program 2** tab.
- Assign the electrode configuration for the program.
 - Tap an electrode to change its polarity to negative (-), positive (+), or off. Tap **Update** when finished.
 - If you need to re-assign the electrodes, first delete all assigned electrodes by tapping the **Select All** button () and then tapping the **Trash** icon ()
- Next, set the stimulation parameters to achieve the desired therapy.
 - Tap the **PULSE WIDTH** control, and use the available options to modify the pulse width value, if desired.
 - Tap the **PROGRAM RATE** control, and use the available options to modify the rate value, if desired.

- Tap the **AMPLITUDE** control, and use the available options to set the amplitude value.
4. (Optional) The perception threshold (PT) may be recorded for future reference. The perception threshold is the amplitude at which the patient perceives the sensation of stimulation.
- Have the patient inform you when the stimulation is perceived. If ramping is being used, tap the **Stop** button (□) when stimulation is perceived. Once the perception threshold is determined, tap the **PT** button (⌚) to record the PT amplitude.
 - Set the amplitude to a comfortable level for the patient.
5. (Optional) If you want to use the electrode redistribution feature, refer to "To use electrode redistribution (to assign percentage of amplitude for individual electrodes)" on page 30.

Setting up Neuro Sense programming

The **SETUP** button on the **Program** screen takes you into the setup tasks on the following screens:

Capture Signal ▶ Review Signal ▶ Configure Thresholds

Note: Once Neuro Sense is set up, any changes to pulse width, rate, or electrodes will delete programmed Neuro Sense settings. Neuro Sense settings will need to be set up again.

To capture body signals and check for a signal of usable size

1. Make sure the programs are created before proceeding. Refer to "Creating programs" on page 40.

2. On the **Program** screen, tap the **SETUP** button.
 3. Start with the patient in a rest position, and then tap the **CAPTURE** button on the **Capture Signal** screen. While data is streaming, have the patient perform a movement or activity that may cause a momentary intense sensation (such as a back arch or cough), and then have the patient return to a rest position.

Note: If the cycling feature is enabled, a notification will display where you can either disable cycling or leave cycling enabled.

 - If you leave cycling enabled, data will not stream during cycling off time. To start cycling on time again, you can either adjust a target amplitude or turn stimulation off and on.
 - If you disable cycling, you will need to re-enable cycling on the **Energy** screen after setup.
 4. To stop streaming data, tap the **STOP** button or wait until the capture stops automatically after 20 seconds (there must be at least 3 seconds of data to determine if the signal is usable).
 5. Review the data in the **SIGNAL SIZE** graph (see Figure 2 on page 38). Make sure that data was captured when the patient was at rest as well as when the patient was performing a movement or activity.
 6. If the label **USABLE SIGNAL SIZE** is shown on the graph, the system uses the captured data to automatically calculate the initial values for the Reaction and Recovery thresholds. You can proceed to step 8.
- (Optional) The **SIGNAL QUALITY PREVIEW** graph shows the waveform for the body signal that is currently selected in the **SIGNAL SIZE** graph. You can drag the signal handle (◀ □ ▶) or tap the arrows to select other body signals and review their waveforms.

7. If the label **UNUSABLE SIGNAL SIZE** is shown on the graph, try the following troubleshooting options. After making a change, re-capture body signal to see if the change elicits a signal of usable size.

- Have the patient try other movements or activities that may cause a momentary intense sensation.
- Increase the Program 1 amplitude if comfortable to the patient.
- Swap the location of the stimulation and sensing electrodes on the lead.
- Move the stimulation and sensing electrodes to the other lead if available.

If none of the troubleshooting options elicit a signal of usable size, then Neuro Sense programming may not be appropriate for the patient.

8. Once a signal of usable size is captured, tap **NEXT** to proceed to the **Review Signal** screen.

To review the quality of the signal

1. On the **Review Signal** screen, review the signal in the **SIGNAL QUALITY** graph (see Figure 3 on page 38).
 - There should be a pronounced low point and a pronounced high point in the curve for the signal to be considered a good signal (refer to on-screen example).
 - The pronounced high point should be in the high point detection window.
 - The pronounced low point should be in the low point detection window.
 - The low point detection window may not include the entire curve of the pronounced low point. Having the

low point detection window at the edge of the curve is acceptable and may avoid signal artifact.

2. If a detection window is not in the correct position, drag the window handle (■) to move it. If you move a detection window, you will need to re-capture body signal on the **Capture Signal** screen and then re-assess the quality of the signal.
3. If there are signal issues due to signal noise, signal artifact, or signal saturation, tap the **Settings** button (⚙️) to access the **ADVANCED SIGNAL SETTINGS** screen. Refer to the on-screen instructions. If you change an advanced signal setting, you will need to re-capture body signal on the **Capture Signal** screen and then re-assess the quality of the signal.
4. Once the quality of the signal has been verified, tap **NEXT** to proceed to the **Configure Thresholds** screen.

To configure thresholds

1. On the **Configure Thresholds** screen, tap the **Active** toggle. This puts Neuro Sense programming in the Active mode where the system senses and measures body signals and makes amplitude adjustments based on those signals.
2. Have the patient perform various activities. Have the patient return to a rest position between each activity.
3. As data is streaming, review the body signal size data in the top graph and the amplitude data in the bottom graph (see Figure 4 on page 39).
4. Ask the patient for feedback about their therapy perception. Assess the patient's feedback when at rest, when performing various activities, and when returning to rest after an activity.
5. If needed, make changes based on the patient's feedback and the troubleshooting information in Table 6 on page 44.

Table 6. Troubleshooting Neuro Sense programming.

Patient Feedback	System Feedback (refer to amplitude graph)	Possible Solutions
When at rest, the perception felt by the patient is more than desired.	Current amplitude is at the target amplitude (solid line is at the dotted line).	Decrease target amplitude.
When at rest, the perception felt by the patient is less than desired.	Current amplitude is at the target amplitude (solid line is at the dotted line).	Increase target amplitude.
	Current amplitude is not returning to target amplitude (solid line never returns to the dotted line).	Increase Recovery threshold.
When at rest, the patient reports pulsating perception.	Amplitude is frequently changing (solid line looks like a saw tooth).	Decrease Recovery threshold. OR Increase Reaction threshold.
During an activity, patient feels discomfort from stimulation.	Amplitude is not decreasing (solid line is at the dotted line) OR amplitude is not decreasing until some time into the activity.	Decrease Reaction threshold.
During an activity, the perception felt by the patient is less than desired.	Amplitude is decreasing too often (solid line is dropping below the dotted line frequently).	Increase Reaction threshold.
	Amplitude is decreasing too much (solid line drops far below the dotted line).	Set Reaction speed to a slower setting.
During an activity, the patient reports pulsating perception.	Amplitude is frequently changing (solid line looks like a saw tooth).	Set Recovery speed to a slower setting. OR Set Reaction speed to a slower setting.
During an activity, patient initially feels uncomfortable perception that transitions to a comfortable level over time.	Amplitude is reducing slowly (solid line drops very slowly from the dotted line).	Set Reaction speed to a faster setting.
When returning to rest after an activity, the patient reports fast increase in stimulation perception or pulsating perception.	Amplitude is returning to target amplitude quickly (solid line quickly returns to dotted line), possibly causing amplitude to reduce again.	Set Recovery speed to a slower setting.
When returning to rest after an activity, the patient feels that it takes a long time to get back to comfortable perception.	Current amplitude is very slow to return to target amplitude (solid line takes a long time to return to the dotted line).	Set Recovery speed to a faster setting.

- To change a target amplitude, tap the **Increase/Decrease** (▲▼) arrows next to the applicable program.

Note: You must first set the toggle to **Sense Only** to change an amplitude. Then set the toggle back to **Active** to assess the change.

By default, the amplitudes adjust separately. Tap the **Link** icon if you want to adjust the amplitudes together. This icon  shows that the amplitudes are linked. This icon  shows that the amplitudes are not linked.

- To change a threshold, use the handle to move the threshold line or tap the **Increase/Decrease** (▲▼) arrows next to the threshold value.

By default, the thresholds adjust separately. Tap the **Link** icon if you want to adjust the thresholds together. This icon  shows that the thresholds are linked. This icon  shows that the thresholds are not linked.

- To change the Reaction speed or the Recovery speed, tap the **Settings** button (⚙️) to access the **ADVANCED NEURO SENSE SETTINGS** screen.

- The Reaction speed is the speed at which stimulation amplitude reduces when the body signal size goes above the Reaction threshold.
- The Recovery speed is the speed at which stimulation amplitude returns to the target amplitude when the body signal size goes below the Recovery threshold.

After making speed adjustments, tap **UPDATE**, and then tap **CLOSE**.

- As needed, tap the **STOP** button to stop data streaming, and tap the **STREAM** button to restart data streaming.

- When data streaming is stopped, the signal handle () appears at the highest body signal on the graph. The size of the body signal is shown, and the corresponding stimulation amplitudes are displayed. You can drag the signal handle or tap the arrows to select other body signals.

- Before leaving the **Configure Thresholds** screen, set Neuro Sense programming to either **Sense Only** or **Active** using the toggle. Then tap **CLOSE**.

Changing the mode of a Neuro Sense group

After a Neuro Sense group is set up, there are three possible modes:

- Active** – The system senses and measures body signals and makes amplitude adjustments based on those signals. In this mode, the patient can disable and enable Neuro Sense programming using the patient control device.
- Sense Only** – The system senses and measures body signals, but no amplitude adjustments are made. In this mode, the patient cannot enable Neuro Sense programming using the patient control device.
- Patient Disabled** – The patient disabled Neuro Sense programming. The system senses and measures body signals, but no amplitude adjustments are made.

To change to the Sense Only mode

- On the **Programs** screen, tap a group name to make it active; then tap the Neuro Sense group summary.
- On the **Configure Thresholds** screen, tap the **Sense Only** toggle, and then tap **CLOSE**.
- Tap **CONFIRM** in the confirmation pop-up.

To change to the Active mode

1. On the **Programs** screen, tap a group name to make it active; then tap the Neuro Sense group summary.
2. On the **Configure Thresholds** screen, tap the **Active** toggle, and then tap **CLOSE**.

Reviewing Neuro Sense data

Neuro Sense data that is captured and stored in the neurostimulator is available for review. This data may be helpful when troubleshooting issues with Neuro Sense programming.

Refer to "Viewing Diaries" on page 67 for information about body signal trend and Neuro Sense usage.

Refer to "Viewing the Neuro Sense Data screen" on page 81 for information about Neuro Sense data accessible from the patient control device.

Customizing SoftStart/Stop™ and Cycling Features

Use the **Energy** screen (accessed from the **Program** screen) to customize the optional device settings for the SoftStart/Stop and Cycling features. These features are designed to increase patient comfort and ease of use.

Changing SoftStart/Stop settings

SoftStart/Stop slowly increases the amplitude when stimulation is turned on and slowly decreases the amplitude when stimulation is turned off. The slow ramping may feel more comfortable to sensitive patients.

SoftStart/Stop is assigned at the group level and applies to all programs within the group. By default, the SoftStart/Stop feature is on with a duration of 4 seconds.

- In the **Energy** screen, use the **SOFTSTART/STOP** drop-down list to select a duration or to turn SoftStart/Stop off.

If AdaptiveStim Technology and SoftStart/Stop are both enabled and the amplitude increases or decreases because of a change in position:

- The amplitude will slowly increase using the ramping programmed for SoftStart/Stop.
- The amplitude will decrease immediately without ramping.

Turning cycling on or off

Cycling turns stimulation on and off at clinician-determined intervals. Due to a carryover effect, the patient may continue to experience symptom suppression during the cycling off time.

Cycling is assigned at the group level and applies to all programs within the group. By default, the cycling feature is off.

1. In the **Energy** screen, tap the **CYCLING** toggle to turn cycling on () or off ()
2. If cycling is on, select the durations for the **ON TIME** and **OFF TIME** intervals.
3. Tap **UPDATE** to apply the changes.

Notes:

- Certain combinations of program rate and cycling duration times may not be allowed by the clinician programmer app. Interlocks may prevent certain cycling duration times from being available for programming.
- Use the **CHECK ENERGY** function in the **Energy** screen to see how cycling affects the recharge interval. Refer to "Estimating Recharge Interval" on page 48.

Estimating Recharge Interval

Use the **CHECK ENERGY** function in the **Energy** screen to estimate the recharge interval for the neurostimulator battery based on the current therapy settings for the active group.

1. Ensure that stimulation is on.
2. For Legacy and DTM SCS groups, ensure that the desired programs in the group are activated. Go to the **Program** screen, and check the **ACTIVATE** toggle for each program.
3. Go to the **Energy** screen, and tap the **CHECK ENERGY** button.
4. Tap the **START CHECK** button.
5. Review the recharge interval estimate, and then tap **OK**.

Note: The recharge interval should be re-estimated if changes are made to programming.

Enabling Patient Access

Use the **Patient Access** screen (accessed from the **Program** screen) to assign patient controls, if appropriate for the patient. There are two patient controls on the **Patient Access** screen: **Adjustment** and **Limits**.

Adjustment

Enabling the **Adjustment** patient control on the **Patient Access** screen allows the patient to increase or decrease amplitude for all programs in the active group at the same time.

Note: By default, the **Adjustment** patient control is enabled.

1. Make sure that the group you intend to configure is shown.
2. Tap the **ALL PROGRAMS TOGETHER** toggle to enable (or disable () the patient control.

For Neuro Sense groups, the **Adjustment** patient control cannot be disabled.

Limits

The **Limits** patient control on the **Patient Access** screen provides the ability to enable or disable patient control of stimulation parameters (amplitude, pulse width, rate). When patient control is enabled for a stimulation parameter, the patient can adjust that stimulation parameter using the patient control device.

If patient control is enabled, the upper patient limit for the stimulation parameter must be assigned. The lower patient limit is set to the lowest possible value by default and is not customizable. Patient control of stimulation parameters is assigned at the group level.

Note: By default, patient control of amplitude is enabled, and patient control of pulse width and rate is disabled.

1. Make sure that the group you intend to configure is shown.
2. Tap the toggle next to the stimulation parameter name to enable () or disable () patient control of the stimulation parameter.
3. For enabled stimulation parameters, set the upper patient limit using any of these controls:
 - Scrollable drop-down list.
 - Dial (press and drag the dot on the dial).
4. After the patient controls are defined, tap **UPDATE**.

Amplitude

- For Legacy and DTM SCS groups, the lowest allowable option for the upper patient limit is determined by the highest amplitude setting in the group's existing programs.
- When AdaptiveStim Technology is enabled for a Legacy or DTM SCS group, patient control of amplitude is automatically enabled and cannot be disabled for that group.
- For Neuro Sense groups, different upper patient limits may apply to each program depending on the stimulation parameters assigned to the programs.

Pulse width

- For DTM SCS and Neuro Sense groups, patient control of pulse width is not available.
- For Legacy groups, the lowest allowable option for the upper patient limit is determined by the highest pulse width setting in the group's existing programs.
- When AdaptiveStim Technology is enabled for a Legacy group, patient control of pulse width is not available.

Rate

- For DTM SCS and Neuro Sense groups, patient control of rate is not available.
- For Legacy groups, the lowest allowable option for the upper patient limit is determined by the current rate setting for the group.
- For Legacy groups, patient control of rate affects the group rate, while rate ratios are maintained for any program rates.

Patient control of rate example

Assume Group A is a Legacy group with three programs, the upper patient limit is set to 200 Hz for the group, and the rates for the programs are assigned by the clinician as follows:

- 100 Hz for Program 1 (group rate)
- 50 Hz for Program 2 (1/2 rate ratio)
- 33 Hz for Program 3 (1/3 rate ratio)

When the patient increases the rate for a program in Group A, the adjustment changes the group rate from 100 Hz to 105 Hz. The new rates for the programs are:

- 105 Hz for Program 1 (group rate)
- 52 Hz for Program 2 (1/2 rate ratio)
- 35 Hz for Program 3 (1/3 rate ratio)

With the upper patient limit set to 200 Hz, the maximum rates for the programs are:

- 200 Hz for Program 1 (group rate)
- 100 Hz for Program 2 (1/2 rate ratio)
- 67 Hz for Program 3 (1/3 rate ratio)

- For Legacy groups, when the cycling feature is enabled and a cycling duration time is less than 0.5 seconds, patient control of rate is not available.

Effect of subsequent parameter changes

- During a subsequent programming session, if a parameter is increased above the upper patient limit, the upper patient limit automatically changes to that new value.

Checking System Performance

The measurement functions on the **Impedance** screen assist in identifying problems with components of the implanted system.

Measurements and diagnostic data obtained from the clinician programmer app are intended to aid in your clinical assessment. However, as with any electronic system, internal and external factors can influence neurostimulator measurements. For example, changes in lead position can affect the stimulation current or the impedance measurement. If you obtain a reading that seems inconsistent with your observations, repeat the measurement.

Note: Measure impedance at the beginning of each programming session. These measurements verify the integrity of lead, extension, and connector pathways. They may provide information about lead problems (such as lead breakage, short circuit, open circuit). For example, measurements that show a significant increase in electrode impedance can indicate a fractured lead conductor or a loose setscrew. Conversely, a significant decrease in electrode impedance can indicate shorted conductors or a break in lead insulation.

Measurements taken at the beginning of the session may be useful in interpreting diagnostic data collected since the previous session.

Testing impedance

The **Impedance** screen is accessed through the workflow navigator.

Note: The **Impedance** screen can be accessed in the Side Menu (≡) when it is not part of a workflow.

1. On the **Impedance** screen, tap the **MEASURE ALL IMPEDANCES** button (Ω).
2. Tap the **START** button on the pop-up screen.
3. After the test is complete, review the impedance results.

Notes:

- If all impedance values are within range, the message "All impedances are within normal range" appears in the **GOOD** box.
- If any impedance value is out of normal ranges (too low or too high), the results appear in either the **AVOID** box or the **DO NOT USE** box. Refer to "Troubleshooting Electrode Impedance Results" on page 52.
- The impedance value shown for each electrode is measured with respect to the selected reference electrode. Use the **REFERENCE ELECTRODE** scrollable drop-down list to select a different reference electrode, if applicable.
- Once an impedance test is performed, results can be viewed at any time during the programming session by returning to the **Impedance** screen. You can also view or print the Session Report, which shows the impedance measurements.

Troubleshooting Electrode Impedance Results

The **AVOID** and **DO NOT USE** boxes on the **Impedance** screen identify where low impedance or high impedance was measured in the system. Refer to Table 7 for more information about impedance results indicators.

Table 7. Impedance results indicators.

Icon	Description
	GOOD (green electrodes with a check mark): Indicates that the impedance measurement value for the electrode is within the normal range (300 - 4,000 ohms).
	AVOID (orange electrodes with an exclamation point): Possible open circuit: <ul style="list-style-type: none">Using these electrodes may increase energy consumption or impact therapy efficacy.Indicates that a high impedance (4,000 - 40,000 ohms) has been detected between electrodes. The Avoid icon is displayed and adjacent to the number of the electrodes where high impedance has been detected. Possible short circuit: <ul style="list-style-type: none">Indicates that a low impedance (under 300 ohms) has been detected between electrodes.The electrode combinations where possible shorts are detected are listed under the text. The electrodes in these combinations will also be listed in the Avoid list.
	DO NOT USE (red electrodes with an "X"): Indicates that there is a strong likelihood of an open circuit (over 40,000 ohms) in the system.

Refer to the troubleshooting details for high impedance and low impedance on the following pages. For further assistance with

troubleshooting electrode impedance results, contact Medtronic using the contact information listed on the back cover of this manual.

Intra-operative troubleshooting

High impedance troubleshooting

High impedance suggests a possible open circuit in the system. High impedance could be caused by a broken wire, loose connection, or highly resistive tissue.

High impedance: >4,000 ohms

- Analyze electrode impedance measurement results. An outlier measurement may indicate an issue with a setscrew or wire. Ensure that all leads and extensions are fully inserted and setscrews are properly tightened and measure impedance again.

For more information about measuring electrode impedance, refer to "Testing impedance" on page 51.
- If a trend towards normal impedance range is not observed, disconnect the lead from the extension (if applicable) and the neurostimulator. Reconnect to the Wireless External Neurostimulator (WENS) and use the A71300 Stimulation Trialing clinician programmer application to test the impedance of the lead alone.
 - Refer to the *A71300 Stimulation Trialing Clinician Programmer Application* programming guide for instructions for measuring impedance with the WENS.
 - If the impedance value is between 300 and 4,000 ohms, then the lead is intact.
 - If the impedance value is greater than 4,000 ohms, visually or fluoroscopically inspect the lead for damage.

3. If lead is intact, reconnect the lead to the extension (if applicable) and use the WENS to test the impedance of the lead and extension together.
 - If the extension impedance value is between 300 and 4,000 ohms, the extension is intact. If the extension impedance value exceeds 4,000 ohms, visually or fluoroscopically inspect the extension and extension connection for damage.
 - If two extensions are being used, switch 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.
4. Reconnect the neurostimulator to the lead and extension (if applicable). Ensure that the neurostimulator is in the pocket and retest the system. If the impedance value remains high, visually or fluoroscopically inspect the connection between the neurostimulator and the lead (or the connection between the neurostimulator and the extension, if applicable) and the neurostimulator connector block for damage.
 - If the neurostimulator impedance value is between 300 and 4,000 ohms, the neurostimulator is intact.
 - If the neurostimulator impedance value exceeds 4,000 ohms, visually or fluoroscopically inspect the neurostimulator and neurostimulator-to-lead (or extension, if applicable) 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.
5. If the previous steps fail to reveal the underlying issue, assess whether it is possible to achieve therapy without using the electrodes with high impedance.
6. If troubleshooting measures fail to resolve the high impedance values, consider substituting new system components as needed.

Low impedance troubleshooting

Low impedance suggests a possible short circuit in the system that can lead to inadequate therapy.

Low impedance: <300 ohms

Avoid using electrodes with a low impedance. Assess whether it is possible to achieve therapy without using the electrodes with low impedance. If the low-impedance electrodes are necessary for programming, revision surgery may be needed.

Post-implant troubleshooting



Caution: 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.

High impedance troubleshooting

High impedance suggests a possible open circuit in the system. High impedance could be caused by a broken wire, loose connection, or highly resistive tissue.

High impedance: >4,000 ohms

Follow these steps to troubleshoot high impedance values:

1. If impedance values are high (>4,000 ohms), consider these troubleshooting options:
 - Assess whether therapy can be achieved using other electrodes.
 - Check for incorrect information. For example, check the **Lead Select** screen to ensure the electrode numbering on the screen matches the electrode numbering of the implanted lead(s).
 - Consider using x-ray to inspect the system components for improper connections or damage.
2. If troubleshooting measures fail to resolve the high impedance values, consider replacing system components as needed.

Low impedance troubleshooting

Low impedance suggests a possible short circuit in the system that can lead to inadequate therapy.

Low impedance: <300 ohms

Avoid using electrodes with a low impedance. Assess whether it is possible to achieve therapy without using the electrodes with low impedance. If the low-impedance electrodes are necessary for programming, revision surgery may be needed.

Preparing System for an MRI Scan

Refer to the *MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain* instructions for use manual for the MRI conditions and MRI-specific warnings and cautions 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.

When the **MRI Mode** feature is activated, stimulation is turned off. Stimulation must be off during the MRI scan.

To check MRI scan eligibility and enter MRI Mode

The information in the **View MRI** workflow impacts the MRI scan eligibility shown on the **MRI** screen.

1. On the **CURRENT DEVICE STATUS** screen, confirm that the patient and device information corresponds with the intended patient and neurostimulator.
2. Tap **VIEW MRI > START**.
3. You are now in the **View MRI** workflow.
Note: You can also access the **MRI** screen on the Side Menu (≡) when not part of a workflow.
4. On the **Device** screen, confirm that the following information is complete and accurate:
 - Neurostimulator model number
 - Neurostimulator implant location

5. On the **Patient Info** screen, confirm that the patient information is complete and accurate.
6. On the **Lead Select** screen, confirm that the lead model numbers are accurate.
7. On the **Tip Location** screen, confirm that the information for the following components is complete and accurate:
 - Presence of abandoned leads, extensions, and pocket adaptors
 - Lead tip location
8. On the **MRI** screen, review the MRI scan eligibility. You will see one of several possible eligibility outcomes, with icons and symbols. Explanations of the outcomes and their icons are described in Table 8.

Do not proceed if eligibility cannot be determined, or if the system is designated as **MR Unsafe**. Contact your Medtronic representative, if needed.

Table 8. 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 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.

Icons shown	Explanation
 	<p>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.</p>
 	<p>MR Unsafe — Patients implanted with a neurostimulation system that is designated as MR Unsafe on the MRI screen are ineligible for MRI scans. Therefore, activating MRI Mode is not applicable for MR Unsafe systems.</p>

9. To prepare the device for an MRI scan, set the **MRI MODE** toggle to Activated (.
10. Confirm that MRI status indicator () displays in the action bar.
11. An MRI report can be generated in the **Reports** screen by selecting **MRI Report** from the drop-down list. Refer to "Working with Reports" on page 69 for details about viewing and printing reports.
Note: If you cannot print your reports, you can manually complete the MRI Eligibility Form in the *MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain* instructions for use manual.
12. Inform the patient of the following:
 - When the **MRI Mode** feature is activated, stimulation is turned off. Stimulation must be off during the MRI scan.
 - Because stimulation is off, pain symptoms may return.
 - Bring the most up-to-date patient ID card to all MRI appointments.

- Bring the patient control device (handset with communicator) to all MRI appointments.
- After the MRI scan is complete and the patient is outside of the magnet room, stimulation can be turned back on using the patient control device. Or, if appropriate, the patient can revisit the clinician after the MRI scan to have stimulation turned back on with the clinician programmer app.

13. Give the MRI Report to the patient or send the report to the MRI center. The MRI clinician uses the MRI Report to confirm the neurostimulator model, session date, patient information, and MRI scan eligibility of the patient's implanted system.

To deactivate MRI Mode

There are two different ways to deactivate MRI Mode and restart stimulation:

1. Start a workflow with the neurostimulator. If the MRI status indicator () displays in the action bar, stimulation will be off.
2. Tap the **Stimulation** toggle in the action bar to turn stimulation on and deactivate MRI Mode.
3. A pop-up message will appear that says turning stimulation on will deactivate MRI Mode. Tap **STIM ON**.
Or
1. From the **MRI** screen, tap the **Deactivated/Activated** toggle.
2. A pop-up message will appear that says deactivating MRI Mode will **not** turn on stimulation automatically. Tap **DEACTIVATE**.
3. Tap the **Stimulation** toggle in the action bar to turn stimulation on.

AdaptiveStim™ Technology

With AdaptiveStim Technology, the Inceptiv neurostimulator can be programmed to adjust amplitude automatically when the patient changes body position. Amplitude settings can be assigned to the following positions: Upright, Mobile, Reclining, Lying Front, Lying Back, Lying Right, Lying Left.

Note: This feature is not available with the Inceptiv LT neurostimulator.

When AdaptiveStim Technology is turned on for a patient, the neurostimulator automatically adjusts the amplitude based on the patient's body position and the clinician-programmed settings. If the patient makes an amplitude adjustment with the patient control device, the neurostimulator associates the new amplitude with the patient's body position as long as the patient stays in that position for at least three minutes. The next time the patient enters that position, the neurostimulator will return to the new amplitude. In this way, AdaptiveStim Technology can respond to patient feedback.

Note: During a programming session, AdaptiveStim settings are not active.

To accommodate the individual needs of the patient, the following AdaptiveStim settings can be adjusted by the clinician:

- **Position angles:** The range or area of a position.
- **Transition times:** The amount of time that must elapse after moving into a new position (and remaining in the new position) before the amplitude will change.
- **Mobility rate:** The intensity of movement that is considered a change from the stationary position of Upright to the moving position of Mobile.

Note: For Neuro Sense groups, configuring position amplitudes is not available, but the neurostimulator can be oriented to patient positions so that position trend data can be gathered.

Caution regarding cervical location

 **Caution:** The use of AdaptiveStim Technology associated with position changes in the cervical location has not been shown to be safe and effective. The use of AdaptiveStim Technology associated with position changes for locations outside of the thoracic or lumbar spine may result in unintended stimulation.

Caution regarding healing period

 **Caution:** Do not configure AdaptiveStim Technology during the implant procedure. A four-week healing period is recommended after implanting the neurostimulator to allow time for the implanted components to stabilize. If the tissue around the neurostimulator is not sufficiently healed, movement of the neurostimulator is possible and may affect orientation.

Caution regarding pulse width or rate changes

 **Caution:** Changing the pulse width or rate in a program may affect AdaptiveStim therapy. Test each of the AdaptiveStim postures in the group for appropriate stimulation after making pulse width or rate changes.

Refer to "To test AdaptiveStim settings" on page 61.

Configuring AdaptiveStim

When you configure AdaptiveStim Technology with the setup wizard, AdaptiveStim Technology is enabled for all programmed groups and every position, including Mobile, no matter what settings were previously assigned to those groups.

When a group is AdaptiveStim-enabled, the AdaptiveStim indicator (ⓘ) appears next to the group name on the **Programs** screen, and patient access for pulse width is not available for that group.

Note: Amplitude limit is automatically enabled when AdaptiveStim Technology is configured for a group and cannot be disabled for that group.

1. Go to the **Programs** screen, and tap a group name to activate the group you want to configure.
2. Select **AdaptiveStim** in the workflow, and tap **Configure** to start the setup wizard.
3. Follow the on-screen instructions for all applicable positions.
 - On the orientation screen, have the patient get in the position, and tap **NEXT** to complete the orientation.
Note: You can tap **SKIP** to bypass certain positions. Orientation still occurs for the position and a position amplitude of zero is assigned to that position.
 - On the programming screen, tap the program you want to configure, and then set the position amplitude using the amplitude control.
 - If applicable, tap another program, and then set the position amplitude. When finished, tap **NEXT** to go to the next position.
4. A confirmation screen will appear when AdaptiveStim Technology has been configured for the group. Tap **CLOSE** to go to the **AdaptiveStim** screen.

Reconfiguring an AdaptiveStim-enabled group

If you want to reconfigure an AdaptiveStim-enabled group, complete these steps to delete the existing AdaptiveStim settings and to reassign position amplitudes for that group. You also have the option to reorient patient positions. To reorient only, refer to "To reorient patient positions" on page 62.

1. Go to the **Programs** screen, and tap a group name to activate the group you want to reconfigure.
2. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙), and then tap **Configure**.
3. Tap **Start Over**.
4. (Optional) Tap the **Reorient** checkbox if you also want to reorient the neurostimulator to the patient positions.
5. Tap **Yes** to proceed.
6. Follow the on-screen instructions to reorient the neurostimulator to the patient positions (if applicable) and to reassign position amplitudes for the programs in the active group.
7. When the wizard is finished, a confirmation screen displays stating that you have successfully reconfigured AdaptiveStim Technology for the group.
8. Tap **CLOSE** to go to the **AdaptiveStim** screen.

What you can do on the AdaptiveStim screen

The **AdaptiveStim** screen displays when an AdaptiveStim-enabled group is the active group and you select **AdaptiveStim** in the workflow. The **AdaptiveStim** screen can also be accessed by tapping

AdaptiveStim on the Side Menu (≡) when not part of a workflow. Refer to Table 9 for information about the tasks you can complete on the **AdaptiveStim** screen.

Note: Some tasks may not be available until AdaptiveStim Technology has been configured.

Table 9. Tasks on the AdaptiveStim screen.

Tasks on the AdaptiveStim screen	More information
Review position amplitudes for all AdaptiveStim-enabled groups. Use this feature to view a summary of the position amplitudes for all AdaptiveStim-enabled groups and programs.	Page 61
Test AdaptiveStim settings. Use this feature to test AdaptiveStim settings during a programming session.	Page 61
Adjust position amplitudes for individual positions. Use this feature to adjust position amplitudes for individual positions in the active group.	Page 61
Check patient positions. Use this feature to determine if the neurostimulator correctly detects the patient positions.	Page 62
Reorient patient positions. Use this feature to reorient the neurostimulator to the patient positions without changing any group settings.	Page 62
Reconfigure an AdaptiveStim-enabled group. Use this feature to delete all existing AdaptiveStim settings for a group and to reassign position amplitudes. You also have the option to reorient patient positions.	Page 58
Disable AdaptiveStim Technology for a group. Use this feature to clear all existing AdaptiveStim settings for a group. All other AdaptiveStim-enabled groups are not impacted.	Page 62
Enable or disable AdaptiveStim Technology for the patient. If the feature is enabled, AdaptiveStim Technology and all assigned settings will be on when the programming session ends. If disabled, AdaptiveStim Technology and all assigned settings will be off when the programming session ends. However, the patient can turn on AdaptiveStim Technology using the patient control device.	Page 62

Table 9. Tasks on the AdaptiveStim screen (continued).

Tasks on the AdaptiveStim screen	More information
Turn the Position Diary on or off. The Position Diary feature enables the Position Trend chart to be populated in the Diaries screen. The Position Trend chart shows the time the patient spent in each position during the periods between the last four programming sessions.	Page 62
Setting stability time Stability time is the amount of time that the patient needs to be in a position before that new intensity for that position will be saved.	Page 63
Adjust position angles. Position angle is the range or area of a position and is used to ensure the neurostimulator properly recognizes the Upright position from the Lying positions.	Page 63
Adjust transition times. Transition time is the amount of time that must elapse between changes in position before the amplitude will change.	Page 63
Adjust mobility rate. Mobility rate is the intensity of movement that is considered a change from the stationary position of Upright to the moving position of Mobile.	Page 64
Turn off mobility detection. Turning off mobility detection disables the Mobile position for AdaptiveStim Technology.	Page 64
Troubleshoot AdaptiveStim Technology. Table 10 lists potential issues that can occur with AdaptiveStim Technology, as well as possible solutions for resolving those issues.	Page 64

To review position amplitudes for all AdaptiveStim-enabled groups

A summary of the position amplitudes for all AdaptiveStim-enabled groups and programs can be viewed from the **AdaptiveStim** screen.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙️), and then tap **Overview**.
2. Review the position amplitudes assigned to the AdaptiveStim-enabled groups. If all groups and programs are not visible, you may need to swipe left or right to see all of the data.
3. Tap **CLOSE** to return to the **AdaptiveStim** screen.

To test AdaptiveStim settings

During a programming session, AdaptiveStim settings are suspended. The **Test AdaptiveStim** feature can be used to test AdaptiveStim settings in session and to obtain patient feedback. There must be at least two different position amplitudes defined in a program to run the test.

1. Go to the **Programs** screen, and tap a group name to activate the group you want to test.
2. Go to the **AdaptiveStim** screen, and tap the **TEST ADAPTIVESTIM** button (⌚).
3. Follow the on-screen instructions to test the AdaptiveStim settings and obtain patient feedback.
4. Tap **STOP** to end the test.

To adjust position amplitudes for individual positions

Complete these steps to adjust position amplitudes for individual positions in a group.

1. Go to the **Programs** screen, and tap a group name to activate the group you want to adjust.
2. Go to the **AdaptiveStim** screen, and tap the position you want to adjust.

On the screen, you see the current programs in the group. Within each program box, the program amplitude is displayed in white and the position amplitude is displayed in green. A white box around a program identifies the active program.
3. Tap the program you want to adjust.
4. Use the amplitude control to adjust the program amplitude (the stimulation the patient is receiving).

The white dot represents the program amplitude. As you make amplitude changes, the white dot moves to reflect the current amplitude.

Note: You can also drag the white dot to assign amplitude. Stimulation ramps up to the amplitude value.
5. When you find an acceptable amplitude, tap **SET POSITION AMPLITUDE** to assign the stimulation the patient is receiving as the position amplitude.

The blue dot represents the position amplitude.
6. When finished making adjustments, tap **CLOSE** to return to the **AdaptiveStim** screen.

To check patient positions

Complete these steps to determine if the neurostimulator correctly detects the patient positions.

1. Place the patient in the position you intend to check.
2. Go to the **AdaptiveStim** screen, and tap the **CHECK POSITION** button (C).
3. Confirm that the position shown on the **AdaptiveStim** screen corresponds to the patient's body position.

To reorient patient positions

Complete these steps to reorient the neurostimulator to the patient positions without changing any group settings.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙), and then tap **Configure**.
2. Tap **Reorient Only**.
3. Tap **Yes** to clear the current orientation.
4. Follow the on-screen instructions to reorient the neurostimulator to the patient positions.
5. (Optional) Tap **SKIP** if you want to bypass a position.
6. When all positions have been reoriented, a confirmation screen displays.
7. Tap **CLOSE** to go to the **AdaptiveStim** screen.

To disable AdaptiveStim Technology for a group

Complete these steps to clear all existing AdaptiveStim settings for a group. All other AdaptiveStim-enabled groups will not be impacted.

1. Go to the **Programs** screen, and tap a group name to activate the group.
2. Go to the **AdaptiveStim** screen, and tap the on/off toggle next to the **Settings** button (⚙) to enable or disable AdaptiveStim.
3. Tap **UPDATE**, and then confirm the disable notification.

To enable or disable AdaptiveStim Technology for the patient

You can choose to either enable or disable AdaptiveStim Technology for the patient. If enabled, AdaptiveStim Technology and all assigned settings will be on when the programming session ends. If disabled, AdaptiveStim Technology and all assigned settings will be off when the programming session ends. However, the patient can turn on AdaptiveStim Technology using the patient control device.

1. Go to the **AdaptiveStim** screen, and tap the **RESUME** on/off toggle to enable or disable AdaptiveStim.
2. Tap **UPDATE** to apply the changes.

To turn the Position Diary on or off

The **Position Diary** feature enables the **Position Trend** chart to be populated in the **Diaries** screen. The **Position Trend** chart shows the time the patient spent in each position during the periods between the last four programming sessions. The chart is accessed through the **Diaries** screen.

AdaptiveStim must be configured for position data to be tracked. Refer to "Configuring AdaptiveStim" on page 57 for instructions. By default, the Position Diary is turned on when AdaptiveStim Technology

is initially configured or reconfigured, or when patient positions are reoriented. If the Position Diary is turned off, from that point, position data is not saved. If the Position Diary is on and AdaptiveStim Technology is turned off, position data continues to be tracked.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙️), and then tap **Settings**.
2. On the **Options** tab under **POSITION DIARY**, tap the on/off toggle. Green (toggle to the right) indicates that the Position Diary is on.
3. Tap **UPDATE** to apply the changes.
4. Tap **CLOSE** to return to the **AdaptiveStim** screen.

To set stability time

The Stability Time setting is the amount of time that the patient needs to be in a position (after having set a new intensity value with the patient control device) before the intensity value for the position is saved to the neurostimulator. The default setting is 0 seconds.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙️), and then tap **Settings**.
2. Tap the **STABILITY TIME** drop-down list and select a duration.
3. Tap **UPDATE** to apply the changes.
4. Tap **CLOSE** to return to the **AdaptiveStim** screen.

To adjust position angles

Position angle is the range or area of a position and is used to ensure that the neurostimulator properly recognizes the Upright position from the Lying positions. By default, the Upright position angle is set

to Small and the Lying position angle is set to XX-Large. All Lying positions (Back, Front, Left, Right) use the same position angle value.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙️), and then tap **Settings**.
2. Tap the **Angles** tab.
3. On the Angles diagram, tap the position name for the angle you want to adjust (for example, **Upright**, **Lying Back**, or **Lying Front**).
4. Press and drag one of the delimiter dots to set a larger or smaller angle.
5. Make other adjustments to the position angles as needed.
6. Tap **UPDATE** to apply the changes.
7. Tap **CLOSE** to return to the **AdaptiveStim** screen.

Note: To test the changes, refer to "To test AdaptiveStim settings" on page 61.

To adjust transition times

Transition time is the amount of time that must elapse between changes in position before the amplitude will change. You can adjust transition times for each position change.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙️), and then tap **Settings**.
2. Tap the **Transitions** tab.
3. Swipe up and down on the screen to scroll and find the position change you want to adjust.
4. Tap to open the scrollable drop-down list and select a duration.
5. Make adjustments to other transition times as needed.

6. Tap **UPDATE** to apply the changes.
7. Tap **CLOSE** to return to the **AdaptiveStim** screen.

Note: To test the changes, refer to "To test AdaptiveStim settings" on page 61.

To adjust mobility rate

Mobility rate is the intensity of movement that is considered a change from the stationary position of Upright to the moving position of Mobile. The mobility rate is only accessible if the Mobile posture is enabled.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙️), and then tap **Settings**.
2. Tap the **Mobility Rate** tab.
3. Confirm that the on/off toggle is in the on position. Green indicates that the Mobile posture is enabled.
4. Press and drag the **Mobility Rate** dot on the slider.
 - **Low (L):** Takes less motion for the neurostimulator to detect the Mobile position.
 - **High (H):** Takes more motion for the neurostimulator to detect the Mobile position.
5. Tap **UPDATE** to apply the changes.
6. Tap **CLOSE** to return to the **AdaptiveStim** screen.

Note: To test the change in mobility rate, refer to "To test AdaptiveStim settings" on page 61. To check patient positions, refer to "To check patient positions" on page 62.

To turn off mobility detection

Turning off mobility detection disables the Mobile position for AdaptiveStim Technology. When mobility detection is off, the Mobile position button is dimmed in the **AdaptiveStim** screen.

1. Go to the **AdaptiveStim** screen, tap the **Settings** button (⚙️), and then tap **Settings**.
2. Tap the **Mobility Rate** tab.
3. Tap the on/off toggle. Gray indicates that the Mobile position is disabled.
4. Tap **UPDATE** to apply the changes.
5. Tap **CLOSE** to return to the **AdaptiveStim** screen.

Troubleshooting AdaptiveStim Technology

Refer to Table 10 for a list of potential issues that can occur with AdaptiveStim Technology, as well as possible solutions for resolving those issues.

Table 10. Troubleshooting AdaptiveStim Technology.

Problem	Possible Solutions
The delay between a position change and the amplitude change is too slow or too fast for the patient.	<ul style="list-style-type: none">■ Use the Transitions setting to increase or decrease the delay between position changes and amplitude changes.■ Use the Test AdaptiveStim feature to obtain patient feedback and make adjustments as needed.
The amplitude changes too often for the patient.	<ul style="list-style-type: none">■ Use the Angles setting to increase the angle for the position that is changing too often. Or■ Use the Transitions setting to increase the delay between position change and amplitude change.
The amplitude changes to the amplitude for the Mobile position while the patient is in the Upright position but not mobile.	<ul style="list-style-type: none">■ Use the Mobility Rate setting to increase the intensity of movement that is required to change to the amplitude for the Mobile position.■ Have the patient remain still in the Upright position for at least one minute.■ Use the Check Position feature to confirm the patient's position. If "Mobile" is shown instead of "Upright" for the patient's current position, increase the mobility rate.
The amplitude does not change to the amplitude for Mobile when the patient is moving.	<ul style="list-style-type: none">■ Use the Mobility Rate setting to decrease the intensity of movement that is required to change to the amplitude for the Mobile position.■ Have the patient walk down the hall for at least one minute.■ Use the Check Position feature to confirm the patient's position. If "Upright" is shown instead of "Mobile" for the patient's current position, decrease the mobility rate.
The patient does not like that the amplitude changes to the Mobile amplitude when starting to walk from the Upright position.	<ul style="list-style-type: none">■ Turn off the Mobility Rate feature.■ When the Mobility Rate feature is turned off, the Mobile position is no longer enabled for AdaptiveStim Technology.
Neurostimulator may have rotated or flipped within the pocket.	<ul style="list-style-type: none">■ Reorient the neurostimulator to the patient positions.

Table 10. Troubleshooting AdaptiveStim Technology (continued).

Problem	Possible Solutions
Patient feels the amplitude for the Upright position when lying down.	<ul style="list-style-type: none">■ Use the Angles setting to increase the angle for the Lying positions.
Patient is not getting adequate therapy in a position programmed with AdaptiveStim.	<ul style="list-style-type: none">■ Review position amplitudes, and check that the position amplitude is not set to 0 mA.
Patient unable to adjust their stimulation rate.	<ul style="list-style-type: none">■ Create multiple identical groups by copying the current AdaptiveStim-enabled group. Adjust the stimulation rate for each group to provide the patient with different stimulation rates with AdaptiveStim enabled. Provide the patient guidance on how to switch groups.

Viewing Diaries

The charts accessed from the **Diaries** screen provide overviews of how the patient is using the neurostimulator.

Stimulation Usage

The **Stimulation Usage** chart shows the patient's stimulation usage. The chart displays the percentage of time per day that stimulation is on over a 30-day period. The metrics provide the average percentage of stimulation usage over the last 30 days and the percentage of time stimulation was on since the last programming session.

Note: If 30 days of stimulation usage data is not available, the calculations are based on the available number of days.

Group Usage

The **Group Usage** chart displays the percentage of time that each group was used since the last programming session.

Recharge

The **Recharge** chart displays the following information for the last 10 recharge sessions:

- Battery recharge percentage at the start and end of the recharge session
- Quality of recharger coupling
- Amount of time for each recharge session

The metrics provide the average ending percentage of battery recharge, the average battery recharge time, the average battery recharge interval, and the median battery recharge coupling value.

Position Trend

The **Position Trend** chart is only applicable to AdaptiveStim Technology. The chart shows the time the patient spent in each position during the periods between the last four programming sessions. The default view shows all positions and the amount of time in percentages.

- Select a position from the scrollable drop-down list if you want to view a specific position only.
- Select **Time** if you want to see the average amount of time per day in hours and minutes.

Adjustments

The **Adjustments** chart is only applicable to AdaptiveStim Technology. The chart shows the number of amplitude adjustments made by the patient since the last programming session. Data is shown for each position and AdaptiveStim-enabled group.

Composite

The **Composite** chart is only applicable to AdaptiveStim Technology. The chart shows the number of hours of stimulation usage for time spent reclining, mobile, upright, and lying within the last 30 days.

- Tap the toggle to display the graph for a specific position on the chart. Multiple positions can be selected to show the position graphs together. Green indicates that the position has been selected.
- The background graph that is displayed (before any position graphs are added) represents stimulation usage.
- Select a start time and end time if you want to see usage during a specific time period.

Resting Trend

The **Resting Trend** chart is only applicable to AdaptiveStim Technology. The chart shows the average number of position changes from one lying position to another during the periods between the last four programming sessions.

Body Signal Trend

The **Body Signal Trend** chart is only applicable to Neuro Sense groups. The chart shows a graphical representation of body signal size values (minimum, median, and maximum) over a 24-hour period for up to 30 days for a specific group.

Neuro Sense Usage

The **Neuro Sense Usage** chart is only applicable to Neuro Sense groups. The chart shows the amount of time the system was controlling amplitude, the amplitude was at target value, and Neuro Sense programming was disabled by the patient or by the system over a 24-hour period for a specific group.

Working with Reports

The following report types are available from the **Reports** screen:

- **Session Report:** Contains information about the settings programmed into the neurostimulator during a programming session as well as therapy usage and system status information.
- **MRI Report:** Contains information intended for MRI clinicians about the MRI scan eligibility of the implanted system for the selected patient.
- **Medtronic Data Report:** Contains information about the Medtronic data collected from the neurostimulator. This report is used by Medtronic personnel when troubleshooting. To compile a Medtronic Data Report, refer to "Compiling a Medtronic Data Report" on page 73.

The **Reports** screen is accessed through the workflow navigator or by tapping **Reports** on the Side Menu (≡) when not part of a workflow. You can also tap **REPORTS** on the initial app screen to view reports for a patient without having to start a session.

Note: Any report generated in Demo mode is labeled **DEMO MODE** at the top of the report.

Using the Reports screen

1. Select a report type from the drop-down list. The default is Session Report.
2. (Optional) Use the filter options to find the patient data you want.
3. Tap the desired patient session record in the scrollable list. The most recent patient session record appears at the top.
4. Tap one of the buttons shown in Table 11.

5. If applicable, tap the checkbox to remove the device serial number from the report, and then tap **CONFIRM**.

Table 11. Report buttons.

Button	Description
	View button – to view the report in PDF format. This action takes you out of the clinician programmer app. The app runs in the background and your session data remains intact.
	Share button – to send the PDF report to another destination. This action takes you out of the clinician programmer app. The app runs in the background and your session data remains intact.
	Download button – to download and save the PDF report on the clinician tablet. This action saves a PDF file in the default reports folder on the clinician tablet.
	Delete button – to delete the selected patient session record from the clinician tablet. When a session record is deleted, the data no longer exists on the clinician tablet. However, deleting a session record does not delete any existing PDF files created from that record and stored on the clinician tablet.

Patient Data Service app

The Patient Data Service app manages the storage of patient session data in a locally stored database on the clinician tablet.

The Patient Data Service app can be used to access or delete patient session data for any patients whose Medtronic devices have been programmed using any clinician programmer app on the clinician tablet.

The Patient Data Service app can also be used to adjust (or disable) the PDF auto-delete feature, which automatically deletes PDF files from the default reports folder on the clinician tablet after a designated amount of time.

Finding and opening the app

1. Navigate to the Apps on the clinician tablet.
2. Find the icon for the **Patient Data Service** app.
3. Tap the icon to open the app.

Accessing or deleting a patient session record

1. In the Patient Data Service app, use the filter options to find the patient data you want.
2. Tap the desired patient session record in the scrollable list. The most recent patient session record appears at the top.
3. Tap one of the buttons shown in Table 12.

Table 12. Patient Data Service buttons.

Button	Description
	Import button – to import the selected session record into the Reports screen in the clinician programmer app. Refer to "Using the Reports screen" on page 69.
	Delete button – to delete the selected patient session record from the clinician tablet. When a session record is deleted, the data no longer exists on the clinician tablet. However, deleting a session record does not delete any existing PDF files created from that record and stored on the clinician tablet.

Deleting multiple patient session records at once

1. In the Patient Data Service app, use the filter options to find the patient data you want.
2. Tap and hold on any record in the results list to activate the multiple record selection feature.
3. Tap the applicable checkboxes to select all records you want to delete from the scrollable list.
4. Tap the **Trash** icon (刪除) to delete the records. The number of records to be deleted is shown next to the icon.
Note: To cancel without deleting records, tap the back arrow in the upper left corner.

Setting the PDF auto-delete feature

Use the auto-delete feature to automatically delete PDF files stored on the clinician tablet based on a timeframe you select. The auto-delete feature is enabled by default with a preset amount of time.

This feature only deletes PDF files from the default reports folder on the clinician tablet. It does not affect patient session data stored in the database.

1. In the Patient Data Service app, tap the **Settings** button (⚙️).
2. Select **PDF Auto Delete**.
3. Select the appropriate auto-delete settings, and then tap **UPDATE**.

Viewing Alerts

The clinician programmer app displays alerts to inform you of specific events or changes in the system. There are three levels of alerts in the clinician programmer app: warning, caution, and information.

When alerts are present, an **ALERTS** button displays on the screen. The button shows the number of alerts that need to be acknowledged. Read and follow the instructions given in the alert.

Working with alerts

- To view alerts, tap the **ALERTS** button in the lower left corner of the screen. Each alert appears in a separate pop-up box.
 - Swipe left or right to view individual alerts.
- To close an alert without dismissing it, tap the **X** (or anywhere outside of the alert pop-up box).
- To dismiss an alert, tap the **DISMISS** button. The alert will be marked as a dismissed alert.
- When all alerts are dismissed, the **ALERTS** button reads "NO ALERTS". Those alerts, however, now exist as dismissed alerts and can still be viewed.
- To view dismissed alerts, tap the **NO ALERTS** button, and then tap the **SHOW DISMISSED** button.
- To restore a dismissed alert, tap the **RESTORE** button.

Viewing System Information

The **About System** screen is accessed from the Side Menu (≡).

This screen provides the following information:

- System information (such as model numbers, serial numbers, firmware numbers, version numbers) for the neurostimulator, clinician tablet, clinician programmer app, controller (patient control device), and communicator.
- Includes information for the controller (patient control device) that most recently communicated with the neurostimulator and the communicator most recently paired with the clinician tablet.
- Trademarks and licenses information.

This screen provides the following capabilities:

- Ability to change the device date and time for the neurostimulator.
- Ability to change the neurostimulator implant date.
- Ability to generate a Medtronic Data Report.

Viewing information about system components

On the **About System** screen, tap the tab for the component information you want to view.

Viewing information about trademarks and licenses

On the **About System** screen, tap the **Licenses** tab, and then tap the button for the information you want to view.

Changing device date/time or implant date information

The **Device** tab on the **About System** screen shows the device date, device time, and implant date. You can change the date and time information if needed.

- Tap the date that you want to change. Use the calendar selector to select a new date, and then tap outside the calendar.
- Tap the time that you want to change. Use the time selector to select a new time, and then tap outside the time.

Compiling a Medtronic Data Report

The **Medtronic Data Report** tab on the **About System** screen is used to compile a report containing information about the Medtronic data collected from the neurostimulator.

- Tap the **COMPILE REPORT** button (↗) to compile the Medtronic Data Report. You cannot cancel the action after it is initiated.

To access previously compiled Medtronic Data Reports, refer to "Working with Reports" on page 69.

Troubleshooting

Approach troubleshooting conservatively. Prior to performing invasive procedures, ensure that all noninvasive solutions have been considered. If additional assistance is needed, contact Medtronic using the contact information listed on the back cover of this manual.

The clinician programmer app displays messages to inform you of issues in the system. Follow the instructions given in the message.

Data validation error message

During initial interrogation, the app performs a data validation check to ensure that the data in the neurostimulator is valid and can be understood. If data is found to be invalid, the app displays a data validation error message and provides the option to clear the invalid data.

Power on reset (POR) message

If a power on reset (POR) message displays at initial interrogation, this indicates that one or more POR events occurred since the last programming session. If a power on reset message displays while in a current programming session, the session will end and any unsaved data will be lost.

Elective Replacement Indicator (ERI) message

When an implanted neurostimulator reaches its elective replacement date, a message displays. Refer to the *System Eligibility and Battery Longevity* reference manual for information about neurostimulator battery longevity.

Stimulation below programmed amplitude message

A message will notify you when the neurostimulator battery is unable to produce the levels of energy required for the current stimulation settings (also known as out-of-regulation or OOR). Generally, this occurs when pulse width or amplitude parameters have been increased beyond what the neurostimulator battery can provide on the programmed electrodes at their present impedance levels.

If this message appears during a programming session, the following are considerations for returning the system settings to programmed amplitude:

1. If this message appears after a parameter has been changed, consider lowering that parameter. Increasing the pulse width and decreasing the amplitude may also resolve the issue.
2. Change the electrodes that are currently providing stimulation. Adding electrodes may help resolve the issue.
3. Consider measuring impedance to see if there is an open or short circuit in the system. Measuring impedance can identify electrodes with lower impedance; switching to these electrodes may resolve the issue.

Using impedance measurements for troubleshooting

Refer to "Checking System Performance" on page 51.

Communicator and clinician tablet troubleshooting

Refer to Table 13 for a list of potential issues that can occur with the communicator or the clinician tablet, as well as possible solutions for resolving those issues.

Table 13. Communicator and clinician tablet troubleshooting.

Problem	Possible Solutions
The communicator cannot communicate with the neurostimulator.	<ul style="list-style-type: none">■ The communicator may not be positioned correctly over the neurostimulator.<ul style="list-style-type: none">– Position the target symbol (⊕) on the back of the communicator so that it is centered over and facing the neurostimulator.■ The communicator may be too far away from the neurostimulator.<ul style="list-style-type: none">– Move the communicator closer to the neurostimulator.■ Metal surfaces can interfere with communication between the communicator and the neurostimulator.<ul style="list-style-type: none">– If the communicator is on a metal table or a metal tray, move the communicator to a nonmetal surface.■ There could be radio-frequency (RF) interference.<ul style="list-style-type: none">– Move the communicator closer to the neurostimulator.■ The communicator may have interrogated a different device.<ul style="list-style-type: none">– Place the communicator directly over the neurostimulator (use a sterile barrier, if applicable), and tap FIND DEVICE on the clinician programmer app.
The communicator cannot pair with the clinician tablet.	<p>BLUETOOTH communication requires an initial pairing with a USB cable. Refer to "Pairing the communicator to the clinician tablet" on page 12 if this initial pairing has not been completed.</p> <p>When attempting to connect through BLUETOOTH wireless technology:</p> <ul style="list-style-type: none">■ Make sure the communicator is turned on and within range of the clinician tablet. See the <i>Model 8880T2 Communicator</i> technical manual for details.■ Make sure that the BLUETOOTH wireless technology is enabled on the clinician tablet. <p>Refer to "Communicator icons on the tablet status bar" on page 16 for what the communicator icons mean when displayed in the tablet status bar.</p>

Table 13. Communicator and clinician tablet troubleshooting (continued).

Problem	Possible Solutions
The communicator cannot communicate wirelessly with the clinician tablet during a programming session.	<p>Possible reasons:</p> <ul style="list-style-type: none"> ■ 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. <p>Possible solutions:</p> <ul style="list-style-type: none"> ■ Use the USB connector cable to connect the communicator to the clinician tablet. ■ Make sure that the BLUETOOTH wireless technology is enabled on the clinician tablet. <p>Refer to "Communicator icons on the tablet status bar" on page 16 for what the communicator icons mean when displayed in the tablet status bar.</p>
The communicator battery level is low.	<ul style="list-style-type: none"> ■ Open the battery case and replace the batteries. <ul style="list-style-type: none"> – If needed, refer to the instructions for replacing the communicator batteries in the <i>Model 8880T2 Communicator</i> technical manual. ■ After replacing the communicator batteries, the clinician programmer app reconnects with the communicator using the BLUETOOTH wireless technology and resumes the session.
The clinician tablet, the clinician programmer app, or the communicator is unresponsive.	<ul style="list-style-type: none"> ■ Turn off the power for the clinician tablet or the communicator, then turn the power on. ■ If you continue to have communication problems or cannot use the app to program, contact Medtronic using the contact information listed on the back cover of this manual.
The communicator is damaged or overheats.	<p>Use a different communicator:</p> <ul style="list-style-type: none"> ■ Ensure that 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. <ul style="list-style-type: none"> – 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.
If the communicator requires repair, is damaged, or is nonfunctional and a replacement is needed, contact Medtronic using the contact information listed on the back cover of this manual.	

Resetting a neurostimulator

To reset a neurostimulator using the app

If a neurostimulator persistently cannot be found and communication to the neurostimulator has been lost, perform the following steps to reset the neurostimulator using the clinician programmer app. Contact the appropriate Medtronic representative listed on the back cover of this manual if additional assistance is needed.

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 NEUROSTIMULATOR(S)** button, then confirm the action.

After sending the reset command, the communicator will beep.

Note: Therapy is automatically stopped after resetting the neurostimulator. To resume therapy, refer to "Initiating communication with the neurostimulator" on page 13.

To reset a neurostimulator using the recharger

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

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

1. Connect the charging dock to a power supply. Place the recharger on the dock as if to charge the recharger.
2. Palpate the patient's skin to determine the approximate location of the neurostimulator.
3. With the recharger on the dock, enter Clinician Reset and Recharge 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 30 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. After performing the clinician reset and recharge, check the therapy status with the clinician programmer app and turn therapy on if necessary.

Patient control device messages

The patient control device displays text and iconic error and informational messages. Some messages tell patients to contact their clinician and provide a service code. These service codes and their

troubleshooting procedures are displayed in Table 14. If additional assistance is needed, contact Medtronic using the contact information listed on the back cover of this manual.

Table 14. Service codes on patient control device indicating the need to contact a clinician.

Service Code	Explanation and Possible Solutions
204	Elective Replacement Indicator An "Elective Replacement (ERI)" alert will display when an implanted neurostimulator has reached its elective replacement date.
303	Patient App Needs Updating A "System Update Needed" alert will display if the patient app is not compatible with the neurostimulator. Confirm that the patient has the correct patient app model for their neurostimulator. Contact Medtronic for instructions for updating the patient app.
306	Patient Attempted to Remove Neurostimulator A "Remove Neurostimulator" alert will display if the user attempts to remove a linked neurostimulator from the About screen in the patient app. A linked neurostimulator is required to use the patient app.
307	Patient Attempted to Remove Communicator A "Remove Communicator" alert will display if the user attempts to remove a linked communicator from the About screen in the patient app. A linked communicator is required to use the patient app with the neurostimulator.
311	Unexpected Command Response An "Error Found" alert will display when an unexpected command response has been detected. Contact Medtronic with the service code if the issue persists.
312	Unexpected Device Status Response An "Error Found" alert will display when an unexpected device status response has been detected. Contact Medtronic with the service code if the issue persists.
316	Therapy Unavailable A "Therapy Unavailable" alert will display when therapy is unavailable due to a battery issue. Check the battery status of the neurostimulator and recharge if needed. Contact Medtronic with the service code if the issue persists.

Table 14. Service codes on patient control device indicating the need to contact a clinician (continued).

Service Code	Explanation and Possible Solutions
318	Invalid Therapy Control Settings An “Update Settings” alert will display if invalid settings are detected. Resolve this issue by updating the neurostimulator settings with the clinician programmer app. If a data validation error message appears upon interrogation, clear the invalid data and reprogram the neurostimulator.
319	No Therapy A “No Therapy” alert will display when the neurostimulator has not been programmed yet with the clinician programmer app.
322	Firmware not Running A “No Therapy” alert will display when a firmware issue has been detected. Contact Medtronic with the service code if the issue persists.
323	Unexpected Therapy Off A “Therapy Off” alert will display when the neurostimulator turned therapy off because it could not deliver the requested level of stimulation. Reprogram the neurostimulator with reduced settings (fewer electrodes and programs; lower amplitude, pulse width, and rate).
324	Unexpected Telemetry Error An “Error Found” alert will display when a telemetry issue has been detected. Contact Medtronic with the service code if the issue persists.
325 326	Invalid Settings An “Invalid Settings” alert will display if invalid settings are detected. Resolve this issue by updating the neurostimulator settings with the clinician programmer app. Verify the settings in each group.

Patient unable to connect to communicator

If the patient persistently encounters the **Not Found** screen and is unable to connect to his or her communicator, it may be because the handset was linked to the wrong communicator during the setup process. In these instances, the patient's handset must be used to remove the link to the wrong communicator before the handset can be linked to the patient's communicator.

To remove a link to a communicator

1. Turn on the patient's handset, and open the patient app.
2. Tap the **Settings** button (⚙️) in the upper right corner, and select **About**.
3. Tap the right arrow button (↗) to navigate to information about the communicator.
4. Tap the **REMOVE COMMUNICATOR** button.
5. Tap the **REMOVE** button on the alert screen that appears.

Now the handset can be linked to the desired communicator.

To link to a communicator

1. Turn on the patient's communicator.
2. Tap the **CONNECT** button on the patient's handset.
3. You can either scan the code on the back of the communicator with the handset camera or enter the serial number manually. Tap either the **SCAN CODE** button or the **ENTER MANUALLY** button and follow the on-screen instructions.

Patient unable to connect to neurostimulator

If the patient persistently encounters the **No Device Response** screen and is unable to connect to his or her neurostimulator, it may be because the handset was linked to the wrong neurostimulator during the setup process. In these instances, the patient's handset must be used to remove the link to the wrong neurostimulator before the handset can be linked to the patient's neurostimulator.

To remove a link to a neurostimulator

1. Turn on the patient's handset, and open the patient app.
2. Tap the **Settings** button (⚙️) in the upper right corner, and select **About**.
3. Tap the right arrow button (↗) to navigate to information about the neurostimulator.
4. Tap the **REMOVE NEUROSTIMULATOR** button.
5. Tap the **REMOVE** button on the alert screen that appears.

Now the handset can be linked to the desired neurostimulator.

To link to a neurostimulator

1. Turn on the patient's communicator.
2. Place the communicator over the patient's neurostimulator.
3. Tap the **CONNECT** button on the patient's handset.
4. Tap the **START** button on the **Setup Link** screen.
5. Compare the serial number displayed on the screen with the serial number of the patient's neurostimulator, and tap **YES** if the serial numbers match.

Viewing the Neuro Sense Data screen

There is a **Neuro Sense Data** screen in the patient app that may be useful for troubleshooting issues with Neuro Sense programming.

1. Turn on the patient's communicator.
2. Turn on the patient's handset, and open the patient app.
3. Tap **CONNECT** on the handset.
4. On the **HOME** screen, make sure the applicable Neuro Sense group is active.
5. Tap the **Menu** (≡) button, and then select **About**.

6. Tap the right arrow button (>) to navigate to information about the neurostimulator.
7. Tap **CHECK NEURO SENSE DATA**.
8. Review the Neuro Sense data as described in Table 15. Data is displayed in three different time frames.
 - **Current partial hour** – Data that is still accumulating during the current hour.
 - **Past full hour** – Accumulated data from the past hour.
 - **Past 24 hours** – Accumulated data from the past 24 hours (including the past full hour).

If needed, tap **Update Data** to refresh the data.

Note: Time is expressed in HH:MM:SS.

Table 15. Neuro Sense Data screen.

Data	Description
Program 1/Program 2	The intensity values currently being delivered by the neurostimulator for Program 1 and Program 2. The larger of these two values is displayed as the intensity on the HOME screen.
Ratio	The “Program 1 : Program 2” values originally set at the clinic. This ratio is maintained between the two programs whenever the patient or Neuro Sense makes any intensity adjustments.
Enabled Time	The amount of time Neuro Sense programming was enabled during the time frame.
Count	The number of times Neuro Sense programming caused a reduction in intensity during the time frame.
Counts/hour	The hourly rate of intensity reductions for each time frame. If Neuro Sense was not active for the entire time frame (patient turned therapy off or Neuro Sense was off temporarily), the counts/hour is adjusted to the rate as if Neuro Sense had been active for the entire time.
Reduction Time	The amount of time the intensity was reduced by Neuro Sense programming during the time frame.
% of time in reduction (Neuro Sense)	The percentage of time the intensity was reduced by Neuro Sense programming during the time frame.

Table 15. Neuro Sense Data screen (continued).

Data	Description
Suspended Time	The amount of time Neuro Sense programming was suspended due to detection of external electromagnetic interference during the time frame.
% of time in reduction (EMI suspend)	The percentage of time Neuro Sense programming was automatically suspended due to external electromagnetic interference during the time frame.

Preparing a Neurostimulator for Explant

Before explanting a neurostimulator, make sure stimulation is off and patient-identifying information is removed from the device. If replacing the neurostimulator, print a session report that shows implanted and any abandoned component information.

1. Start a session with the neurostimulator, and select the **FOLLOWUP** workflow.
2. If necessary, tap the **Stimulation** toggle to turn stimulation off ().
3. If replacing the neurostimulator, go to the **Reports** screen, and print a current session report.
4. Tap the **Menu** () button, and then select **Patient Info**.
5. Replace the patient's name with an **x** in the **FIRST NAME** and **LAST NAME** fields.
6. Tap **UPDATE**.
7. Go to the **Summary** screen, and tap **EXIT WORKFLOW**.

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