CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use
This device is intended to help clinicians program stimulation parameters for St. Jude Medical™ neurostimulation systems and create customized therapy for patients.

Additional Prescription Information
Refer to the clinician's manual for the appropriate neurostimulation system to get additional prescription information, including indications for use and contraindications. For specific instructions, warnings, precautions, and adverse effects about other system components, see the clinician’s manual for those components.

MRI Safety Information
For more information about MR Conditional neurostimulation components and systems, including equipment settings, scanning procedures, and a complete listing of conditionally approved components, refer to the MRI procedures clinician's manual for neurostimulation systems (available online at manuals.sjm.com). For more information about MR Conditional products, visit the St. Jude Medical product information page at sjmprofessional.com/MRI.
Do not bring the clinician programmer into a scanner magnet room. It can be affected by the MRI magnet, may present a projectile hazard, and is considered MR Unsafe.

**Warnings**
The following warnings apply to these components.

**NOTE:**

**System components.** The use of non-St. Jude Medical components with this system may result in damage to the system and increased risk to the patient.

**Application modification.** To prevent unintended stimulation, do not modify the operating system in any way. Do not use the application if the operating system is compromised (i.e., jailbroken).

**Precautions**
The following precautions apply to these components.

**NOTE:**
Device Precautions

Nonsterile device. The medical device system comprised of the programmer and other St. Jude Medical devices as specified in this document must be used in accordance with IEC 60601-1 for patient programming. This device is a nonsterile device and must be kept out of the sterile field (patient environment).

Device inspection. Before operating the system each time, inspect the device and all its components for mechanical and electrical integrity. Avoid using the system if the device or its components are damaged. Return damaged components to St. Jude Medical for evaluation.

Handle the device with care. The device is a sensitive electronic device that can be damaged by rough handling, such as dropping it on the ground.

Device modification. To prevent damage to the system, do not modify the device in any way.

Application Precautions

Clinician training. Clinicians should be familiar with neurostimulation therapy and be experienced diagnosing and treating the indication for which the neurostimulation system components are being used.

Electromagnetic interference (EMI). Certain types of equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction
furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

**Wireless use restrictions.** In some environments, the use of wireless functions (e.g., Bluetooth®) may be restricted. Such restrictions may apply aboard airplanes, in hospitals, near explosives, or in hazardous locations. If you are unsure of the policy that applies to the use of this device, please ask for authorization to use it before turning it on.

**High stimulation outputs.** Stimulation at high outputs may cause unpleasant sensations or motor disturbances, or render the patient incapable of controlling the stimulator. If unpleasant sensations occur, the device should be turned off immediately.

**Product Description**

The St. Jude Medical™ Clinician Programmer app (Model 3874) interfaces with St. Jude Medical™ neurostimulation systems and is intended to be used to noninvasively program and control device parameters. The St. Jude Medical™ Clinician Programmer communicates wirelessly with the generator.

**NOTE:**

For more information about the neurostimulation system, see the clinician’s manual for the compatible components.
NOTE:
In this document, the term "clinician programmer" refers to the St. Jude Medical™ Clinician Programmer device, "patient controller" refers to the St. Jude Medical™ Patient Controller device, "clinician programmer app" refers to the St. Jude Medical™ Clinician Programmer app, and "patient controller app" refers to the St. Jude Medical™ Patient Controller app.

Overview of the Clinician Programmer
Refer to the following figure for the clinician programmer features.

NOTE:
For non-therapy related information on how to use the clinician programmer, refer to the Apple manual available at http://www.apple.com/support/ipad/.
Figure 1. Clinician programmer features

1. Power button
2. Home button
Table 1. Clinician programmer feature descriptions

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power button</td>
<td>To turn the clinician programmer on, press and hold the Power button until the Apple icon appears.</td>
</tr>
<tr>
<td></td>
<td>To turn the clinician programmer off, press and hold the Power button until the slide to power off bar appears, and then slide the bar to the right.</td>
</tr>
<tr>
<td></td>
<td>To wake the clinician programmer from sleep mode, press the Power button.</td>
</tr>
<tr>
<td></td>
<td>To unlock the clinician programmer, slide the slide to unlock bar to the right.</td>
</tr>
<tr>
<td></td>
<td>To place the clinician programmer in sleep mode, press the Power button.</td>
</tr>
<tr>
<td>Home button</td>
<td>Press the Home button to return to the Home screen.</td>
</tr>
<tr>
<td></td>
<td>To wake the clinician programmer from sleep mode, press the Home button.</td>
</tr>
<tr>
<td>Touch screen swipe</td>
<td>To swipe the screen to the right, touch the left side of the screen and briefly drag your finger to the right side, and then lift your finger from the screen. Use the same general steps to swipe the screen left, up, or down.</td>
</tr>
<tr>
<td>functionality</td>
<td></td>
</tr>
</tbody>
</table>
Getting Started
This section contains information about navigating the Home screen and instructions for pairing and connecting the clinician programmer to a generator.

Downloading the Clinician Programmer App

NOTE:

The minimum system requirements for the clinician programmer app is an Apple iPad mini 2 with retina display running iOS 8.1 or later. The minimum system requirements for the patient controller app is an Apple iPod touch 5th generation running iOS 8.1 or later.

NOTE:

Install the apps well before you need to use them in case you encounter network or server issues.

NOTE:

Do not install additional applications on the clinician programmer. Only upgrade the iOS when instructed to do so by St. Jude Medical.

The following information outlines the steps for downloading the clinician programmer. For instructions on downloading the patient controller app, see the user’s guide.
1. Make sure the device is connected to the internet and has a strong connection (full bars on Wi-Fi or at least three bars on Cellular).
2. Enter the following web address in your web browser: https://sjm.awmdm.com

   **NOTE:**
   Most devices will already have the web address bookmarked.
3. When prompted, enter the Group ID.

   **NOTE:**
   The Group ID varies depending on where the device is used. Refer to Appendix A for the Group ID for your location.
4. Enter your St. Jude Medical username and passcode.
   You may wait a minute or longer while the device connects to the server.
5. Tap **Install** on the Install Profile screen.
6. Tap **Install** when prompted to Install Profile.
8. Tap **Trust** on the Remote Management screen.
9. Tap **Done** on the Profile Installed screen.
10. Exit your web browser when you reach the Enrollment Complete screen.
    The app icon automatically appears on the device Home screen, though it may take a few
minutes. If the app icon does not appear after a few minutes, use the following steps:
1. Tap  on the Home screen.
The App Catalog screen opens.
2. Tap the Internal tab.
You will see the clinician programmer app.
3. Tap Install.
4. Tap Install when prompted.
It may take a few minutes for the app to appear on the Home screen.

Navigating the Home Screen
When you start a session with the clinician programmer app, the Home screen appears. From the Home screen, you can access the following areas.

- Tap Generators to locate a generator for programming.
- Tap Patient Records to open the patient records screen.
- Tap Demonstration Mode to open a software demonstration.
- Tap  to open the Information popover where you can view clinician and programmer information, as well as create and email a programmer log.
NOTE:

The first time you launch the clinician programmer app, the Legal Notices popover opens. Tap Agree to use the app. To view the legal notices again, tap Legal Notices in the Programmer Information popover.

NOTE:

The clinician programmer app times out after 30 minutes of inactivity; however, if you navigate away from the app (i.e., press the Home button), the app times out after 3 minutes of inactivity.

Pairing the Clinician Programmer to the Generator

Pairing is when you set up communication between the clinician programmer or patient controller and generator. The following instructions outline the steps for pairing the clinician programmer to the generator. For further instructions, refer to the clinician’s manual for the generator.

NOTE:

If the IPG has never established communication with a programmer, you must first activate the IPG for communication ("wake up" the IPG) by holding a magnet over the IPG for 8 seconds.
NOTE:

You cannot pair the generator to the clinician programmer if the generator is currently communicating with the patient controller. See Troubleshooting (page 56) for instructions on ending the session early.

1. Place the magnet perpendicular to the generator for 10 seconds.
   If pairing with an External Pulse Generator (EPG), the indicator light on the generator will start flashing.

2. Tap **Generators** on the app Home screen.
   The Select Generator popover opens.

3. Select an available generator. A green unlock icon is displayed over the generator if the generator is ready to pair.
   If no generators are found, you will see the No Supported Generators Found message. Tap ![refresh] to search for available generators again and refresh the generator list.

1. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.
2. Tap **Pair** to pair the clinician programmer and generator.

Once you have paired the clinician programmer to a generator, you will not need to pair the clinician programmer to that generator again unless more than four clinician programmers also pair with the generator.
Pairing the Patient Controller to the Generator

The following instructions outline the steps for pairing the patient controller to the generator. For further instructions, refer to the clinician’s manual for the generator.

NOTE:

You cannot pair the generator to the patient controller if the generator is currently communicating with the clinician programmer. Tap Done and then End Session in the clinician programmer app to end the session.

1. Place the magnet perpendicular to the generator for 10 seconds.
   If pairing with an EPG, the indicator light on the generator will start flashing.
2. Tap the patient controller app.
   The patient controller app launches.
3. Tap an available generator in the "Select a Generator..." list.
   If no generators are found, you will see the No Generators Found message. Tap to search for available generators again and refresh the generator list.
4. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.
5. Tap Pair to pair the patient controller and generator.
   The "Connecting to Generator..." message displays while the patient controller is connecting to the generator.
NOTE:

Store paired patient controllers and trial generators together to reduce the number of times you need to set up communication.

You may pair the patient controller with up to four different generators. The following instructions outline the steps for deleting a generator from a patient controller.

1. On the Generators screen, tap **Edit**.
2. Tap ☒ next to the generator you want to delete.
   The Delete button appears next to the generator.
3. Tap **Delete**.
   A confirmation pops up.
4. Tap **Delete** to remove the generator.

Programming with the Clinician Programmer App

This section provides instructions and information about programming using the clinician programmer app.

**NOTE:**

Some functionality included in the manual may be unavailable in your region. Consult your local representative for more information.
Navigating the Program Screen
The Program screen opens once you successfully connect to a generator. See the "Switching Between Tonic Mode and Burst Mode" section for more information.

Buttons and Icons on the Program Screens and Popovers
The following table provides definitions for buttons and icons that you may encounter.

NOTE:
Not all buttons or icons will be available on all screens.

Table 2. Program screen descriptions

<table>
<thead>
<tr>
<th>Button or Icon</th>
<th>Button or Icon Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![i]</td>
<td>Patient Information button</td>
<td>Tap to view or edit patient information.</td>
</tr>
<tr>
<td>![on]</td>
<td>Generator Icon</td>
<td>Tap to view generator information.</td>
</tr>
<tr>
<td>Revert</td>
<td>Revert button</td>
<td>Tap to revert to the last saved program settings.</td>
</tr>
<tr>
<td><img src="add" alt="+" /></td>
<td>Add/Copy Program button</td>
<td>Tap to add or copy a program.</td>
</tr>
<tr>
<td>Program 1</td>
<td>Program Name button</td>
<td>Tap to view and edit the list of available programs.</td>
</tr>
<tr>
<td>Button or Icon</td>
<td>Button or Icon Name</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Manage Programs button</td>
<td>Tap to change the active program options.</td>
</tr>
<tr>
<td>Done</td>
<td>Done button</td>
<td>On the Program screen, tap to save the program and end the session. On a popover, tap to save changes and return to the previous screen or popover.</td>
</tr>
<tr>
<td></td>
<td>Add Area or Pulse button</td>
<td>Tap to add an area or pulse to the program.</td>
</tr>
<tr>
<td></td>
<td>Area Options button</td>
<td>Tap to edit a name, delete an area, and balance. (Tonic only)</td>
</tr>
<tr>
<td></td>
<td>Minus button</td>
<td>Tap to decrease the number of pulses (Burst only)</td>
</tr>
<tr>
<td>Edit</td>
<td>Edit button</td>
<td>Tap to edit the lead diagram settings.</td>
</tr>
<tr>
<td></td>
<td>Electrode button</td>
<td>Tap to change the electrode settings.</td>
</tr>
<tr>
<td></td>
<td>Up button</td>
<td>Shift the electrode polarities up. This feature is only available with certain lead types.</td>
</tr>
<tr>
<td></td>
<td>Down button</td>
<td>Shift the electrode polarities down. This feature is only available with certain lead types.</td>
</tr>
<tr>
<td></td>
<td>Up button</td>
<td>Use the MultiSteering programming feature to steer the electrical field up.</td>
</tr>
<tr>
<td>Button or Icon</td>
<td>Button or Icon Name</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>🚪</td>
<td>Down button</td>
<td>Use the MultiSteering programming feature to steer the electrical field down.</td>
</tr>
<tr>
<td>⬅</td>
<td>Left button</td>
<td>Use the MultiSteering programming feature to steer the electrical field left.</td>
</tr>
<tr>
<td>➡</td>
<td>Right button</td>
<td>Use the MultiSteering programming feature to steer the electrical field right.</td>
</tr>
<tr>
<td>🤖</td>
<td>Generator anode button</td>
<td>Tap to change the generator to anode. This option removes anodes from the leads. (IPG only)</td>
</tr>
<tr>
<td>📚</td>
<td>Program Options button (at bottom of screen)</td>
<td>Tap to view, select, or delete the programs on the generator communicating with the clinician programmer app.</td>
</tr>
<tr>
<td>⚡</td>
<td>Stop stimulation button</td>
<td>Tap to stop stimulation</td>
</tr>
<tr>
<td>🗑️</td>
<td>Clear button</td>
<td>Tap to clear the contents of a text field</td>
</tr>
<tr>
<td>🐶</td>
<td>Delete button control</td>
<td>Tap to reveal or hide the Delete button</td>
</tr>
<tr>
<td>🔄</td>
<td>Reset button</td>
<td>Tap to reset to the most recently saved settings</td>
</tr>
<tr>
<td>Back</td>
<td>Back button</td>
<td>Tap to save changes and return to the previous screen or popover</td>
</tr>
<tr>
<td>Button or Icon</td>
<td>Button or Icon Name</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cancel</td>
<td>Cancel button</td>
<td>Tap to discard changes and return to the previous screen or popover</td>
</tr>
<tr>
<td>Share report</td>
<td>Share report button</td>
<td>Tap to email or print the report.</td>
</tr>
</tbody>
</table>

**Creating a New Programming Session**

**NOTE:**

Programs that use higher pulse width, frequency, or amplitude settings deplete the generator battery faster.

To start a new programming session, follow these steps:

1. Tap **Generators** on the Home screen.
   The Select Generator popover opens.
2. Select an available generator. A patient name is displayed under the generator previously associated with a patient if the clinician programmer was used to program this generator before.
   - Swipe up or down to display more available generators, if applicable.
3. If this is a trial generator, tap **New Trial** or **Continue Trial** on the "Continue Trial or Start New Trial?" popover.
The Program screen opens.
4. Set the desired parameters. See the corresponding sections in this manual for instructions.
5. Enter patient information as needed. See "Managing Patient Records" for more information.
6. When finished, tap Done and End Session.

Reassigning a Generator

When starting a new trial you have the option to reassign a generator to a new patient. The records for the previous patient assigned to the generator are retained in the patient records.

To reassign a generator to a new patient, perform the following:
1. Tap New Trial on the "Continue Trial or Start New Trial?" popover.
   The generator is assigned to a default patient.
2. From the Program screen, tap 📄. The Patient popover opens.
3. Edit the default patient information to create a new patient.
4. Tap Done.

When creating a programming session for a new patient, you may assign the generator to an existing patient by editing the default patient information.

To assign the generator to an existing patient, follow these steps:
1. From the Program screen, tap 📄. The Patient popover opens.
2. Tap Select a Patient. The Select a Patient popover opens.
- Tap in the Search field and enter a patient's first or last name to search for a patient.
- Swipe to scroll through the patient list.

3. Tap a patient name to select that patient.
4. Tap < Back and then Done to return to the Patient popover.

**Selecting the Lead Configuration**

**NOTE:**

If a lead model is an approved MR Conditional component, an MR Conditional icon is displayed beside the model number. If you select an MR Conditional lead, a message appears asking if a lead extension is used with the system. Tap Yes or No appropriately because this information is critical for determining if all the implanted components meet the MR Conditional requirements.

To add a lead, follow these steps:
1. Tap Edit on the Program screen.
2. Tap +.
   The Lead Options popover opens.
3. Tap Type.
   The Type popover opens.
   From the Type popover, you have the following options for adding a lead:
- Search for a lead using a partial model name or model number
- Tap the model name and then select the model number from the popover
- Tap **Scan Bar Code** to scan the bar code on the lead packaging using the bar code scanner

4. Tap outside the popover to save changes and close the popover.

To select the patient’s lead configuration, follow these steps:
1. On the Program screen, tap **Edit** in the lead diagram area.
2. Tap + to add a lead to the first available port.

To remove the lead:
1. Tap ✗.
   The Delete Lead popover opens.
2. Tap **Delete Lead** to remove the lead or outside the popover to cancel removing the lead.

To edit the lead options:
1. Tap the lead to open the Lead Options popover.
2. Set the desired lead options.

**NOTE:**

A 16 channel lead only allows the Reverse Ports option, not the Port option.
NOTE:

If you change the lead configuration, you may need to delete existing programs.

3. Tap Done or tap outside the popover to save changes and close the popover.

Configuring Electrode Polarities

Individual electrodes on a lead may be set to positive (anode), negative (cathode) or neutral.

NOTE:

If you manually change polarities while stimulation is active, stimulation turns off and the perception and comfort amplitude values clear on tonic programs or the target amplitude value clears on burst programs. Additionally, any previous area impedance results clear as well.

To configure electrode polarities, follow these steps:

- On the Program screen, tap a numbered electrode button on the lead diagram.
  The electrode popover opens.
  - Tap – (Cathode) to set the electrode to cathode.
  - Tap + (Anode) to set the electrode to anode.
  - Tap outside the electrode popover to close the popover.
- Tap OFF to turn the electrode off.

**NOTE:**

The anode option is unavailable for leads if the generator is set to function as an anode.

**Switching Between Tonic Mode and Burst Mode**

On the clinician programmer app you may create and modify two types of programs:

- **Tonic program.** A program where the stimulation frequency consists of a single, repeating pulse.
- **Burst program.** A program where the stimulation frequency consists of a group of pulses in rapid succession followed by a period without pulses before repeating the group.

You may switch to burst programming mode on the Program screen.

**NOTE:**

When creating a new program, you start programming in tonic programming mode by default.

**NOTE:**

When you switch between burst mode and tonic mode, all programmed values reset to default except the electrode configuration.
To switch between tonic mode and burst mode, follow these steps:
1. On the Program screen, tap  to open the Program Options popover.
2. Tap the Burst Mode switch to switch between tonic stimulation and burst stimulation.
   - Off (switch to the left, white), means tonic stimulation is selected
   - On (switch to the right, green), means burst stimulation is selected
3. Tap Change to confirm switching the program mode.
   When burst mode is active, the Program screen displays the features for burst programming.

**Adjusting Pulse Width**
When creating a new program, the Pulse Width box on the Program screen displays a default value, which is determined by programming mode (tonic or burst).
To change the pulse width value, do either of the following:
- Tap the Up or Down buttons next to the Pulse Width box.
- Tap the Pulse Width box, and then tap a value in the Pulse Width popover.

**Adjusting Amplitude and Step Size**
On the Program screen, you may adjust amplitude and step size. Amplitude is the strength of the electrical pulse that is delivered from the lead. Step size is the increment at which amplitude will change when you adjust amplitude.
NOTE:
At any time you can immediately stop the patient’s stimulation by tapping ⚡.

NOTE:
When the generator reaches its energy or charge limit, a notification appears. Try reducing the frequency, pulse width, and amplitude.

NOTE:
When the generator reaches its output limit, the parameter boxes will turn yellow. Amplitude may still be increased, but the program cannot be saved. To reduce the output of the generator, try reducing the amplitude or pulse width or try setting additional anodes or cathodes on the lead configuration.

To adjust amplitude, perform the following actions:

- If stimulation is off, tap the Up button next to the Amplitude box to start stimulation.
- To change the step size, tap and drag the slider to the right or left to increase or decrease the step size accordingly. This determines how much the amplitude is increased or decreased when adjusting amplitude.
- Tap the Up or Down buttons next to the Amplitude box to increase or decrease stimulation accordingly.
Setting the Patient Controller Custom Settings
The system creates default patient controller app maximum output based on program settings, then autopopulates the Patient Controller area accordingly. You may override the recommended value and customize the output the patient controller app allows.

To customize the output for the patient controller app, follow these steps:
1. Tap the Patient Controller box to open the Patient Controller popover.
2. Tap the Use Custom Settings switch and select the maximum amplitude for the patient controller app.
3. Tap Done or tap outside the popover to save changes and close the popover.

Adjusting Frequency for Tonic Programs
When creating new tonic programs, the Frequency box on the Program screen displays a default value. To change the frequency value, do either of the following:
- Tap the Up or Down buttons next to the Frequency box.
- Tap the Frequency box, and then tap a value in the Frequency popover.

NOTE:
The buttons are not available when the programmed maximum (Up) or minimum (Down) frequency is reached.
Setting Perception and Comfort Amplitudes for Tonic Programs

To complete a tonic program, you must set values for perception and comfort amplitudes for each area. The perception amplitude is the value at which the patient first feels stimulation. The comfort amplitude is the value at which the stimulation feels comfortable to the patient.

NOTE:

When the generator reaches its output limit, the parameter boxes will turn yellow and you cannot set perception and comfort amplitude values. To reduce the output of the generator, try reducing the amplitude or setting additional anodes or cathodes on the lead configuration.

NOTE:

If you change electrode polarities after you have set the values for perception and comfort amplitude, the perception and comfort amplitude values will clear.

To set a patient’s perception and comfort amplitudes, follow these steps:

1. Tap the Perception box to open the Perception popover and set the patient’s perception amplitude.
2. Tap the Comfort box to open the Comfort popover and set the patient’s comfort amplitude.

NOTE:

Once you have set the perception and comfort amplitudes, you can tap **Ramp to – mA**.
(where "--" is the perception or comfort amplitude) in the Perception and Comfort popovers to ramp the amplitude to the perception or comfort value.

**Adjusting Frequency for Burst Programs**

Burst programs have two adjustable frequency values: the overall frequency (Burst Frequency) and the frequency of each individual pulse in a pulse group (Intra-burst Rate). When creating new burst programs, the Burst Rate and Intra-burst boxes on the Program screen display system default values. To change the frequency values for a burst program, do either of the following:

- Tap the Up or Down buttons next to the respective box.
- Tap the respective box, and then tap a value in the popover.

**Setting the Target Amplitude for Burst Programs**

To complete a burst program, you must set the value for the target amplitude. The target amplitude is the value at which stimulation feels comfortable to the patient.

**NOTE:**

When the generator reaches its output limit, the parameter boxes will turn yellow and you cannot set the target amplitude value. To reduce the output of the generator, try reducing the amplitude or pulse width or try setting additional anodes or cathodes on the lead configuration.
NOTE:
If you change electrode polarities after you have set the value for target amplitude, the target amplitude value will clear.

NOTE:
Once you have set the target amplitude, you can tap **Ramp to – mA** (where "--" is the target amplitude) in the Target popover to ramp the amplitude to the target value.

To set a patient’s target amplitude, do the following:
- Tap the Target box to open the Target popover and set the amplitude where the patient feels comfortable stimulation.

**Adding an Area or a Burst Pulse to a Program**

To add another area to a tonic program or another burst pulse to a burst program, follow these steps:
1. On the Program screen, tap + in the Area or Pulses section.
2. Set the stimulation parameters as needed.

**Editing an Area in a Program**

To delete or rename an area in a tonic program, follow these steps:
1. On the Program screen, tap ∈ to open the Areas section.
2. Tap Edit in the Areas popover.
   - Tap 🗑️ to delete an area name.
   - Tap the area name to rename the area using the keyboard.

   NOTE:

   Areas are automatically numbered unless you enter a custom name. Duplicate names are not allowed.

Decreasing the Number of Burst Pulses
To decrease the number of burst pulses in a burst program, do the following:

- On the Program screen, tap ← to decrease the number of pulses by 1.

   NOTE:

   The minimum number of pulses is 2.

Creating a Stimulation Map
You may create a stimulation map to show where the patient senses stimulation with a specific stimulation set for tonic programs or with a pulse group for burst programs. The stimulation map also appears on the user’s patient controller app.
To create a stimulation map, follow these steps:

1. On the Program screen, tap the Stim Map. The Map popover opens with a graphic representation of the human body.
2. Tap the areas on the graphic that correspond to the areas where the patient is receiving stimulation. To select multiple areas, tap and drag on the stim map. The tapped areas are highlighted in blue.
3. To remove a highlighted area, tap the area on the stim map. To remove multiple areas, tap and drag on the stim map.
4. To save the stimulation map and return to the Program screen, tap **Done**.
5. To cancel any changes and return to the Program screen, tap **Cancel**.

**Measuring Impedance**

While programming you may want to periodically measure the impedance on the electrode array as a diagnostic tool to ensure that current is flowing through the system properly. Impedance measurements may help you troubleshoot issues with the neurostimulation system.

**NOTE:**

If electrodes on the Program screen turn yellow, your impedance measurement is high or low. See "Troubleshooting" (page 56) for more information.
To measure impedance for the programmed electrode array, follow these steps:

1. Tap the Impedance box to open the Check Impedance popover.
2. Tap **Program** to check the impedance on the electrode configuration for the current program. Impedance is checked and the value is displayed in the Impedance box.
3. Tap **System** to check the impedance on the lead configuration.
   - Tap **Start** to start an impedance check on all electrodes.
   - Tap an electrode to open the popover with the impedance results for that electrode.
   - Tap **Done** to exit the Full System impedance view.
4. Tap **System (90 Days)** to check the system impedance for the last 90 days.
   **NOTE:**
   This feature is only visible after you turn on automatic impedance logging on the Generator screen. Turning on this feature will briefly turn patient stimulation off every 23 hours.
   The 90 Day Impedance Report is displayed.
   a. Tap [ ] to open the Share popover.
   b. Tap [ ] to email or tap [ ] to print a PDF of the report.
5. When you are finished, tap outside the popover to return to the Program screen.
Using the Shifting Programming Feature
The Shifting programming feature, which is only available with certain lead types, provides a simplified method for setting the electrode configuration by moving the entire electrode combinations up or down as a unit. Shifting can continue past the upper and lower boundaries of the lead, resulting in any electrodes moved beyond the boundary to be removed from the electrode combinations. During Shifting programming, stimulation is turned off.

To use the Shifting programming feature:
- Configure electrode polarities until the Shifting buttons become active.
- Tap the Shifting buttons to steer the electrode array.

**NOTE:**
When you use Shifting programming, both the programmed perception and comfort amplitudes automatically clear.

Using the MultiSteering Programming Feature
The MultiSteering™ programming feature provides a simplified method for shaping and fine-tuning the electrical field in real time. During MultiSteering programming, certain electrode combinations can be moved while stimulation remains active.
To use the MultiSteering programming feature:

- Configure electrode polarities until the MultiSteering buttons become active.
- Tap the MultiSteering buttons to steer the stimulation through a set of optimized electrode combinations designed to incrementally shift stimulation.

**NOTE:**

When you use MultiSteering programming the programmed comfort amplitude automatically clears.

- Tap the Amplitude box to open the Auto Decrement popover.
  - The default is Set Amplitude to Perception. This option lowers the amplitude to perception when electrodes are changed using MultiSteering programming.
  - Tap **Do Not Change Amplitude** to keep the amplitude the same when electrodes are changed using MultiSteering programming.

**NOTE:**

Adjust the amplitude to the patient’s perception level (Perc) or lower each time before steering to the next combination since some nerve fibers may be more sensitive to electrical fields than others.
Adding a New Program

To add a new program, follow these steps:
1. On the Program screen, tap \[\text{+_} \].
2. Tap \textbf{Add New Program} in the popover. A new program is automatically named according to the next available number.
3. Set the desired parameters.

\textbf{NOTE:}

The Program screen defaults to tonic programming mode when you create a new program.

Changing the Active Program

To change the active program, follow these steps:
1. On the Program screen, tap the program name.
   The Programs popover opens.
2. Tap a program in the list.
   The selected program becomes the active program.
Copying a Selected Program
To copy the active program, follow these steps:
1. On the Program screen, tap `➕`.
2. Tap **Copy Active Program** in the popover. The duplicated program appears as the next available program number.

Renaming a Selected Program
To rename a program, follow these steps:
1. On Program screen, tap the program name. The Programs popover opens.
2. Tap **Edit**. The Programs popover changes to edit mode.
3. Tap the program name you want to rename. The Edit Name popover opens.
4. Enter a custom name.
5. Tap ✖ to clear the program name field.
6. Tap < or outside the popover to save changes and close the popover.

Deleting a Selected Program
To delete a program, follow these steps:
1. On Program screen, tap the program name. The Programs popover opens.
2. Tap **Edit**. The Programs popover changes to edit mode.
3. Tap ‡ next to the program you want to delete. The Delete button appears.
4. Tap **Delete**.
   If all programs are deleted, the popover closes and a default program is created; otherwise, the selected program is deleted.
5. Tap **Done** or outside the popover to save changes and close the popover.

**NOTE:**

You can also delete an area or a burst pulse on the Program screen. See the "Editing an Area in a Program" or "Decreasing the Number of Burst Pulses" section for more information.

**Modifying Program Options**

You may modify the active program options by performing the following functions:

- Tap **≡** at the bottom of the Program screen to open the Program Options screen. The Program Options screen includes:
  - Set the burst mode (visible if Burst Mode is unlocked)
  - Set the program mode
  - Set the on and off times for cycle mode
  - Set the step size increment
  - Set the on time for sleep mode (EPG only)
To modify program options, follow these steps:
1. On the Program Options screen, modify the settings as desired. The following subsections provide more information about using these settings.
2. When you are finished, tap Done or tap outside the popover to save changes and close the popover.

To Set the Program Mode
You can set the stimulation mode of a program. The following table provides definitions of the program modes that may be available.

Table 3. Definitions of Program Modes

<table>
<thead>
<tr>
<th>Mode</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous</td>
<td>Stimulation is delivered continuously while the generator is on and the program is running.</td>
</tr>
<tr>
<td>Cycle</td>
<td>Stimulation is on for a programmed amount of time (on time) and off for a programmed amount of time (off time). The cycle alternates between on and off time until the generator is turned off or the program is stopped.</td>
</tr>
</tbody>
</table>
Sleep Stimulation is on for a programmed amount of time (on time), after which stimulation turns off and stays off until stimulation is manually turned on. (EPG only)

To set the program mode, follow these steps:
1. Tap **Program Mode** on the Program Options screen.
2. Tap the desired program mode.
   - If you tap Cycle, On Time and Off Time becomes available on the Program Options screen.
   - For the EPG, if you tap Sleep, On Time becomes available on the Program Options screen.

**To Set the On Time and Off Time**
The On Time and Off Time setting controls the amount of time stimulation is on and off.

To set the on and off time, follow these steps:
1. Tap **On Time** or **Off Time** on the Program Options screen.
   The On & Off Time popover opens.
2. Tap the + and – buttons to increase or decrease the time.
3. Tap **Back** or outside the popover to save any changes and return to Program Options.

**NOTE:**
You can set the on and off cycle times to a minimum of 2 seconds (5 seconds for the EPG)
and a maximum of 24 hours. For the EPG, you can set the on sleep time to a minimum of 1 minute and a maximum of 18 hours.

To Set the Step Size Increment
The step size increment setting controls what step sizes are available when you adjust the amplitude. To set the step size increment, follow these steps:
1. Tap **Step Size Increment** on the Program Options screen.
   The Step Size Increment popover opens.
2. Tap the desired step size increment.
3. Tap **Back** or outside the popover to save any changes and return to Program Options.

To Set the Magnet Mode
The magnet mode setting controls how the generator responds when it senses a magnet. To set the magnet mode, tap **Magnet** to open the Magnet popover:
- Tap **Disabled** to disable magnet mode so stimulation is unaffected if the generator senses a magnet. (IPG only)
- Tap **Turns Stimulation On/Off** to turn generator stimulation on or off each time the generator senses a magnet
- Tap **Turns Stimulation Off Only** to turn generator stimulation off when the generator senses a magnet
Tap Back or outside the popover to save any changes and return to Program Options.

To Set the Ramp Time
Ramp time is the approximate number of seconds that the generator takes when starting stimulation to arrive at the perception amplitude for tonic programs or the target amplitude for burst programs and is only available in continuous program mode. This ramp time is used when stimulation is turned on using the patient controller; it is not the ramp time that you use while programming. The default ramp time is 4 seconds.

To change the ramp time, follow these steps:
1. Tap Ramp Time on the Program Options popover. The Ramp Time popover opens.
2. Tap on the desired ramp time from the list. To scroll to a ramp time that is not displayed, swipe up or down on the screen.
3. Tap Back or outside the popover to save any changes and return to Program Options.

Using the Active Balancing Programming Feature
The Active Balancing™ programming feature allows you to adjust the amplitude of all the stim sets within a program at the same time or individually, which helps balance the feeling of stimulation delivered to a patient.
NOTE:

This feature is available only for tonic stimulation programs. Active Balancing is not available until Perception and Comfort amplitudes are set for two or more areas.

To balance a program, follow these steps:

1. On the Program screen, tap 📚 next to Areas to open the Areas popover.
2. In the Areas popover, tap **Balance** to open the Active Balancing popover.
3. Tap the Increase button beside the master amplitude box. The amplitude ramps up to the perception value (Perc).

   **NOTE:**

   To stop stimulation, tap 🌠. This button turns off the master amplitude, disables the area increase and decrease buttons, and grays out the level indicator bars.

4. Tap the Increase and Decrease buttons to adjust the master amplitude until the patient indicates that stimulation is comfortable.
5. Tap the Increase and Decrease buttons in an area to increase or decrease the amplitude level of an area.

   **NOTE:**

   If an overhead state is detected, the Maximum Generator Output Reached alert pops up and the green level indicator bars turn yellow for the areas in overhead. You cannot save the
program if it is in overhead.

**NOTE:**

To reset all sliders to zero, tap 🔄.

6. If the program contains more than four areas, scroll down to display the remaining areas and adjust the areas if necessary.

7. Tap **Done**.

**Saving a Program**

When you complete programming, you must save the program before viewing the Session Summary Report.

1. To save the program, tap **Done** on the Program screen.
2. Tap **End Session** in the popover.

**NOTE:**

When you save the program, it is automatically saved to the generator.

**NOTE:**

During intraoperative testing, you do not need to save the program. To exit an intraoperative testing session and return to the Home screen, tap **Done** and then **End Session** on the
Program screen. When asked by the system if you want to delete the program, tap Yes.

NOTE:

If any parameters of a stim set are incomplete for a program, a message appears when you try to save the program. To correct this issue, ensure that you have configured valid electrode polarity combinations and have set all stimulation parameters.

Managing Programs on the Generator

After completing a programming session, you can view, select, or delete the programs on the generator communicating with the clinician programmer app.

1. Tap next to the program name on the Program screen. The Manage Programs popover opens.
2. Tap Manage Programs to open the list of available programs.

The list of available programs opens, with the currently active program selected by default.

To view an overview of the program settings, do the following:

- Tap a program name on the list.
  - A green check mark appears next to the active program name and the program details are displayed.

To rename a program on the list, follow these steps:

1. Tap Edit.
2. Tap a program name and enter the custom program name.
3. Tap < Back to return to the Edit screen.
4. Tap Done to save changes and return to the Program screen.

To select a program as the active program, follow these steps:
1. Tap a program name on the list.
2. Tap Select.
   The Program screen opens for the selected program.

   NOTE:
   
   If the selected program is not valid, an alert pops up notifying you the program must be fixed or deleted before another program can be edited.

To delete a program on the list, follow these steps:
1. Tap Edit.
2. Tap next to the program you want to delete. The Delete button appears.
3. Tap Delete.
   If all programs are deleted, the popover closes and a default program is created.
4. Tap Done to save changes and return to the Programs screen.

Viewing Generator Details
The Generator popover provides information about the generator, such as the total amount of time...
stimulation has been on for the generator.

From the Generator popover, you may perform the following actions:

- View information about the generator, such as the model and serial number on the About popover.
- Install new generator software from the About popover.
- Change the generator name on the Edit Name popover. This name is displayed on the generators list for both the clinician and patient.
- Change the implant date on the Implant Date popover (IPG only).
- View how long stimulation has been on.
- View the remaining generator battery charge.
- Set an IPG into MRI mode, if applicable. (If any of the implanted components are not MR Conditional, **MRI is Not Permitted** is displayed instead of the **MRI Mode** option.)
- Turn on impedance logging. See "Measuring Impedance" (page 31) for more information (IPG only).
- Download and send a generator log, which contains information such as how stimulation was used, that may help when troubleshooting.

To view the generator details, perform the following:

- Tap the generator icon on the Program screen.
  The Generator popover opens.

When a new generator software version is available you will receive a message notifying you it is
included with the new clinician programmer app version. Additionally, you will receive a message when
you connect to the generator if you have not installed the new version yet.

To install the new generator software, do either of the following:

- Tap Update in the "Update Generator Software" message.
- Tap Install Software in the About popover.

**NOTE:**

Make sure the clinician programmer is charged before installing the generator software. Do
not close the app, lock the clinician programmer, or interrupt communication while installing
the generator software or the generator may become unresponsive.

To create and send a generator log, follow these steps:

1. Tap **Email Generator Diagnostic Log** on the Generator popover.
   The popover closes. You will see a "Exporting Log File" system message while the system is
generating the log file and email.
2. Enter the email address.

**NOTE:**

Configure mail support before using the Email Generator Diagnostic Log functionality.

To set an applicable IPG into MRI mode, follow these steps:

1. Tap **MRI Mode** on the Generator popover. The MRI Mode popover opens.
2. Tap the **MRI Mode** switch.
3. When the "Set Generator to MRI Mode" message appears, tap **Continue**. Stimulation stops, and the clinician programmer app checks the system for any issues. If the checks are successful, a message appears indicating that IPG is in MRI mode.

**NOTE:**

If a warning screen appears indicating that MRI is not advised, you cannot set the IPG to MRI mode and the patient cannot receive and MRI scan. Refer to "Troubleshooting" (page 56) for more information.

**NOTE:**

If MRI mode is on, you will not be able to perform any programming actions. Tap **Exit MRI Mode** on the screen message to disable MRI mode. Otherwise, end the programming session.

### Managing Patient Records

The patient records screen displays the device history for each patient, including indication, device and system information, session history, stimulation settings, and usage diagnostics. The clinician programmer app allows you to manage patient records by adding or deleting patient data. Tap **Patient Records** on the clinician programmer app Home screen to open the patient records screen.
NOTE:
Patient information is not displayed on the right side of the screen until a patient is selected.

Buttons and Icons on the Patient Records Screens and Popovers
The following table provides definitions for buttons and icons that you may encounter while managing patient records.

NOTE:
Not all buttons or icons will be available on all screens.

Table 4. Buttons and icons on the patient records screens

<table>
<thead>
<tr>
<th>Button or Icon</th>
<th>Button or Icon Name</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home button</td>
<td>Home button</td>
<td>Tap to go to the clinician programmer app Home screen</td>
</tr>
<tr>
<td>Edit</td>
<td>Edit patient list button</td>
<td>Tap to edit the patient list</td>
</tr>
<tr>
<td>Add patient button</td>
<td>Add patient button</td>
<td>Tap to add a patient</td>
</tr>
<tr>
<td>Patient information button</td>
<td>Patient information button</td>
<td>Tap to view patient information</td>
</tr>
<tr>
<td>Action</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>Delete patient button</td>
<td>Tap to delete the patient</td>
<td></td>
</tr>
<tr>
<td>Name Search field</td>
<td>Tap to search for a patient name</td>
<td></td>
</tr>
<tr>
<td>Patient name in patient list</td>
<td>Tap to open the patient overview for the selected patient</td>
<td></td>
</tr>
<tr>
<td>Delete generator button</td>
<td>Tap to delete the generator</td>
<td></td>
</tr>
<tr>
<td>Generator Backup button</td>
<td>Tap to email the backup file. (Only available when a backup file exists.)</td>
<td></td>
</tr>
<tr>
<td>Sessions</td>
<td>Tap to view the session history list</td>
<td></td>
</tr>
<tr>
<td>Diagnostics</td>
<td>Tap to view the diagnostics history list</td>
<td></td>
</tr>
<tr>
<td>Session detail button</td>
<td>Tap to open the selected session summary</td>
<td></td>
</tr>
<tr>
<td>Clear button</td>
<td>Tap to clear the contents of a text field</td>
<td></td>
</tr>
<tr>
<td>Cancel button</td>
<td>Tap to cancel the action and close the popover</td>
<td></td>
</tr>
<tr>
<td>Share report button</td>
<td>Tap to email or print the report</td>
<td></td>
</tr>
<tr>
<td>Email button</td>
<td>Tap to email the report</td>
<td></td>
</tr>
<tr>
<td>Print button</td>
<td>Tap to print the report</td>
<td></td>
</tr>
</tbody>
</table>
Adding a Patient
To add a patient, follow these steps:
1. From the patient records screen, tap Add. The New Patient popover opens.
   NOTE:
   The Add button is not available until you enter a first name.
2. Tap a field you want to complete and enter the information using the on-screen keyboard.
3. Tap Add to save the patient’s information and return to the Patients screen.

Editing a Patient’s Information
To edit a patient’s information, follow these steps:
1. From the Program screen, tap Edit. The Patient popover opens.
2. Tap Edit.
   The Patient popover changes to the editable state.
3. Tap a field you want to complete and enter the information using the on-screen keyboard.
4. Tap Done to save the changes and return to the Program screen.
Deleting a Patient from the Database

To delete a patient from the database, follow these steps:

1. On the Patients screen, tap Edit.
   The patient list changes to the editable state.
2. Tap a patient name to select or unselect a patient. If a patient is selected, a check mark will appear to the left of their name. You may select multiple patients to delete.
3. Tap Delete, then tap Delete Patient.

Viewing, Emailing, and Printing a Report

Two types of reports are available on the patient records screen, the Session report and the Diagnostics report. A Session report is automatically generated and opens when you end a programming session. This report provides information such as the programmed stimulation settings and information about how stimulation was used since the programs were last modified. The Diagnostics report provides system impedance information. You may email or print the reports. For information about the 90 Day Diagnostics report, see the "Measuring Impedance" section.

- Swipe up or down to scroll through information for all the programs.

NOTE:

If a program was not saved to the generator, a message will appear under the program name.
NOTE:

Configure mail support before using the email report functionality.

To generate a Session report, follow these steps:
1. Tap **Sessions** on the right hand side of the screen.
2. Select a session date.
3. Swipe up or down to scroll through and view the program information.
4. Tap 📄 to open the Share popover.
5. Tap ⚡ to email or tap 📄 to print a PDF of the report.

To generate a Diagnostics report, follow these steps:
1. Tap **Diagnostics** on the right hand side of the screen.
2. Select a session date.
3. Tap 📄 to open the Share popover.
4. Tap ⚡ to email or tap 📄 to print a PDF of the report.

Checking the Generator Battery Status

You can view the current generator battery status for the EPG in the generator icon on the Program screen and in the Generator popover for the EPG and IPG. As the battery is used, the generator icon shows the remaining charge as shown in the figure below. The Generator popover displays the
remaining percent for the EPG battery or remaining life for the IPG battery. Battery life depends on communication usage and stimulation settings. For instance, programs with multiple stimulation areas or higher outputs will drain the battery faster.

**NOTE:**

The remaining life for the IPG battery is calculated from recent stimulation and communication usage. If usage habits change for a period of time, this will affect the remaining battery life calculation. Additionally, if there is not enough recent usage data available, the Generator popover will display N/A. For more information, refer to the clinician’s manual for the generator.

Figure 2. Generator battery indicator progression

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NOTE:

- When the remaining generator battery charge reaches 2 or 1 (for the trial system) or 1 or 0 (for the permanent system), a warning pops up on your clinician programmer app.
- When the generator battery is too low to support stimulation (0), generator stimulation automatically turns off and the clinician programmer app ends the programming session. If applicable, replace the generator batteries to connect and communicate with the generator.

NOTE:

You may also receive low battery warnings regarding the clinician programmer, so make sure to read the warning before dismissing.

Maintaining the Clinician Programmer

This section provides tips and other information to help you maintain the clinician programmer.

Checking the Clinician Programmer Battery Status

You can view the clinician programmer battery status in the top right corner of the screen. As the battery is used, the battery indicator shows the remaining charge. Recharge the clinician programmer using the provided Apple charging cord.
NOTE:
Keep the clinician programmer charged or have a power supply nearby. Familiarize yourself with the clinician programmer’s battery life. For further information, refer to the Apple manual available at http://www.apple.com/support/ipad/.

Caring for the Clinician Programmer

NOTE:
For information on how to care for the clinician programmer, refer to the Apple manual available at http://www.apple.com/support/ipad/.

Troubleshooting

This section provides troubleshooting suggestions for issues you may experience with the clinician programmer or clinician programmer app. For additional information, call Technical Support. When you call, be ready to give the representative information about what you were doing when the error occurred and what error messages appeared. See the "Viewing Generator Details" section for instructions about creating a generator log.

NOTE:
If your device is lost or damaged, contact Technical Support.
Troubleshooting Chart

Typically, the clinician programmer app displays a message for issues associated with programming patients and managing records. If you are experiencing issues, check the clinician programmer app screen for a message and follow any instructions it gives to correct the issue. If you still experience the issue or if you experience an issue without receiving an on-screen message, refer to the following table for possible causes and solutions.

Table 5. Possible causes and solutions for potential issues

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Possible Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician programmer has no power or has lost power.</td>
<td>Clinician programmer’s battery is drained.</td>
<td>Recharge the battery using the charger.</td>
</tr>
<tr>
<td></td>
<td>Clinician programmer is damaged or malfunctioning.</td>
<td>Replace the clinician programmer.</td>
</tr>
<tr>
<td>Clinician programmer will not charge.</td>
<td>Charger is disconnected from the clinician programmer.</td>
<td>Connect the charger to the clinician programmer.</td>
</tr>
<tr>
<td></td>
<td>Correct plug adapter (voltage converter) is not connected to the charger.</td>
<td>Connect the appropriate plug adapter (voltage converter) to the charger.</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Charger is defective.</td>
<td>Replace the charger.</td>
<td></td>
</tr>
<tr>
<td>Clinician programmer is</td>
<td>Replace the clinician programmer.</td>
<td></td>
</tr>
<tr>
<td>damaged or malfunctioning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nothing is displayed on the</td>
<td>Clinician programmer is off or has timed out.</td>
<td>Turn on the clinician programmer.</td>
</tr>
<tr>
<td>screen.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinician programmer’s battery is drained.</td>
<td>Recharge the battery using the charger.</td>
<td></td>
</tr>
<tr>
<td>Screen is damaged or</td>
<td>If the clinician programmer appears to be powered on but without display, the screen may be defective. Contact Technical Support.</td>
<td></td>
</tr>
<tr>
<td>malfunctioning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Clinician programmer will not respond to input.</td>
<td>Clinician programmer has locked up.</td>
<td>Perform a soft reset.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Press and hold the Power button until the <em>slide to power off</em> bar appears.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Slide the bar to the right.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Press and hold the Power button until the Apple icon appears.</td>
</tr>
<tr>
<td>Touch-screen interface is damaged or malfunctioning.</td>
<td>Replace the clinician programmer.</td>
<td></td>
</tr>
<tr>
<td>Clinician programmer battery is drained.</td>
<td>Charge the clinician programmer battery.</td>
<td></td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Bluetooth connection is not strong or turned off.</td>
<td>Decrease the distance between the devices.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Move the devices away from other devices that may be causing interference.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Move the devices so they share line of sight.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Do not operate other wireless devices at the same time.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wait a few minutes and try connecting again.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Turn Bluetooth on using the iOS settings.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Press the clinician programmer Home button.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Tap Settings on the clinician programmer Home screen.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Tap Bluetooth, and then tap the Bluetooth toggle button.</td>
<td></td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>---------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Clinician programmer is damaged or malfunctioning.</td>
<td>Replace the clinician programmer.</td>
<td></td>
</tr>
<tr>
<td>Patient is not receiving stimulation.</td>
<td>Stimulation is off.</td>
<td>Turn on stimulation using the patient controller app.</td>
</tr>
<tr>
<td>Generator battery is low and stimulation shut off.</td>
<td>Replace the EPG batteries. For more information, refer to the clinician’s manual for the generator.</td>
<td></td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-----------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lead is damaged or has become</td>
<td>Check impedance on the lead using the clinician</td>
<td>Replace the generator. Contact Technical Support.</td>
</tr>
<tr>
<td>disconnected.</td>
<td>programmer app. If impedance is high, then the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>lead may be damaged or disconnected. Check the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>connections or consider replacing the lead. For</td>
<td></td>
</tr>
<tr>
<td></td>
<td>more information, refer to the clinician’s manual</td>
<td></td>
</tr>
<tr>
<td></td>
<td>for the applicable components. Refer to &quot;Measuring</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Impedance&quot; (page 31) for more information.</td>
<td></td>
</tr>
<tr>
<td>Generator is damaged or</td>
<td>Replace the generator. Contact Technical Support.</td>
<td></td>
</tr>
<tr>
<td>malfunctioning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>---------</td>
<td>---------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Parameter boxes on the Program screen turn yellow.</td>
<td>Generator has reached its output limit and is in overhead.</td>
<td>You may test stimulation while the generator is in overhead, but you cannot save the program. Reduce the amplitude or pulse width. OR Set additional polarities (anode or cathode) on the lead.</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lead is damaged or has become disconnected.</td>
<td>Check impedance on the lead using the clinician programmer app. If impedance remains high despite changes to program settings, then the lead may be damaged or disconnected. Check the connections or consider replacing the lead. For more information, refer to the clinician’s manual for the applicable components. Refer to &quot;Measuring Impedance&quot; (page 31) for more information.</td>
<td></td>
</tr>
<tr>
<td>Cannot locate clinician programmer app.</td>
<td>Clinician programmer app is not on clinician programmer Home screen.</td>
<td>Swipe through screens from the Home screen to locate app. Search for the app using iOS search functionality.</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>MRI is Not Permitted is displayed instead of the MRI Mode option on the Generator popover.</td>
<td>A part of the implanted system is not MR Conditional.</td>
<td>Confirm the implanted models of the system. If any implanted part is not MR Conditional, the patient cannot receive an MRI scan.</td>
</tr>
<tr>
<td>MRI Mode option is not available on the Generator popover.</td>
<td>The IPG is not connected to the clinician programmer.</td>
<td>Try connecting to the IPG again.</td>
</tr>
<tr>
<td>MRI is Not Advised message appears while trying to set the IPG to MRI mode.</td>
<td>A problem occurred during the system checks while setting MRI mode.</td>
<td>The IPG is not in MRI mode, and an MRI scan cannot be performed</td>
</tr>
<tr>
<td>Generator software upgrade was not successful.</td>
<td>Generator software upgrade was interrupted.</td>
<td>Try installing the generator software again.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If you cannot locate the generator on the clinician programmer app, contact Technical Support.</td>
</tr>
<tr>
<td>Problem</td>
<td>Possible Cause</td>
<td>Possible Solution</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Cannot locate programs after upgrading generator software.</td>
<td>After installing generator software, the previous program data was lost.</td>
<td>1. On the patient records screen, locate the patient history.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Reprogram the patient.</td>
</tr>
</tbody>
</table>

### Technical Support

For technical questions and support for your St. Jude Medical™ neuromodulation product, use the following information:

- +1 972 309 8000
- +1 800 727 7846 (toll-free within North America)

For additional assistance, call your local St. Jude Medical representative.
Appendix A: Group ID List

Following is the Group ID list you will use when installing the clinician programmer app and patient controller app.

Table 6. Group ID list

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Group ID</th>
<th>Country/Region</th>
<th>Group ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Algeria</td>
<td>PRODDZA</td>
<td>Lebanon</td>
<td>PRODLBN</td>
</tr>
<tr>
<td>Argentina</td>
<td>PRODARG</td>
<td>Luxembourg</td>
<td>PRODEU</td>
</tr>
<tr>
<td>Australia</td>
<td>PRODAUSNZ</td>
<td>Malaysia</td>
<td>PRODMYS</td>
</tr>
<tr>
<td>Austria</td>
<td>PRODEU</td>
<td>Mexico</td>
<td>PRODMEX</td>
</tr>
<tr>
<td>Belgium</td>
<td>PRODEU</td>
<td>Netherlands</td>
<td>PRODEU</td>
</tr>
<tr>
<td>Brazil</td>
<td>PRODBRA</td>
<td>New Zealand</td>
<td>PRODAUSNZ</td>
</tr>
<tr>
<td>Canada</td>
<td>PRODCAN</td>
<td>Norway</td>
<td>PRODNOR</td>
</tr>
<tr>
<td>Chile</td>
<td>PRODCHL</td>
<td>Panama</td>
<td>PRODPAN</td>
</tr>
<tr>
<td>China</td>
<td>PRODCHN</td>
<td>Peru</td>
<td>PRODPER</td>
</tr>
<tr>
<td>Colombia</td>
<td>PRODCOL</td>
<td>Poland</td>
<td>PRODEU</td>
</tr>
<tr>
<td>Country</td>
<td>Code</td>
<td>Country</td>
<td>Code</td>
</tr>
<tr>
<td>--------------</td>
<td>----------</td>
<td>--------------</td>
<td>----------</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>PRODCRI</td>
<td>Portugal</td>
<td>PRODEU</td>
</tr>
<tr>
<td>Cyprus</td>
<td>PRODEU</td>
<td>Puerto Rico</td>
<td>PRODPRI</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>PRODEU</td>
<td>Russia</td>
<td>PRODRUS</td>
</tr>
<tr>
<td>Denmark</td>
<td>PRODEU</td>
<td>Saudi Arabia</td>
<td>PRODSAU</td>
</tr>
<tr>
<td>Ecuador</td>
<td>PRODECU</td>
<td>Singapore</td>
<td>PRODSGP</td>
</tr>
<tr>
<td>Finland</td>
<td>PRODEU</td>
<td>South Africa</td>
<td>PRODZAF</td>
</tr>
<tr>
<td>France</td>
<td>PRODEU</td>
<td>South Korea</td>
<td>PRODKOR</td>
</tr>
<tr>
<td>Germany</td>
<td>PRODEU</td>
<td>Spain</td>
<td>PRODEU</td>
</tr>
<tr>
<td>Greece</td>
<td>PRODEU</td>
<td>Sweden</td>
<td>PRODEU</td>
</tr>
<tr>
<td>Iceland</td>
<td>PRODISL</td>
<td>Switzerland</td>
<td>PRODEU</td>
</tr>
<tr>
<td>India</td>
<td>PRODIND</td>
<td>Taiwan</td>
<td>PRODTWN</td>
</tr>
<tr>
<td>Ireland</td>
<td>PRODEU</td>
<td>Thailand</td>
<td>PRODTHA</td>
</tr>
<tr>
<td>Israel</td>
<td>PRODISR</td>
<td>Turkey</td>
<td>PRODTUR</td>
</tr>
<tr>
<td>Italy</td>
<td>PRODEU</td>
<td>UK</td>
<td>PRODEU</td>
</tr>
<tr>
<td>Japan</td>
<td>PRODJPN</td>
<td>US</td>
<td>PRODUSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Country Not Listed</td>
<td>PRODOTHER</td>
</tr>
</tbody>
</table>
Appendix B: Regulatory Statements

NOTE:


Appendix C: Symbols and Definitions

The following symbols may be used in this document and on some of the products and packaging:

NOTE:


<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Caution, Consult Accompanying Documents</td>
</tr>
<tr>
<td>🚨</td>
<td>Denotes that the user must consult this document for important safety-related information (This symbol is blue and white on the device.)</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Authorized European representative</td>
</tr>
</tbody>
</table>

European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.

Appendix D: CE Mark Date

Table 7. Year in which the CE mark was awarded.

<table>
<thead>
<tr>
<th>Model</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>3874</td>
<td>2015</td>
</tr>
</tbody>
</table>