St. Jude Medical™ Clinician Programmer

For Spinal Cord Stimulation Systems
Model 3874

Clinician's Manual

Abbott

Contents

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

The St. Jude Medical™ Clinician Programmer and St. Jude Medical™ Patient Controller Applications are intended to communicate with pulse generators to manage stimulation programs. The applications allow clinicians to create customized therapy and help patients manage their prescribed stimulation programs.

Intended Users

The intended users for this application are clinicians who assist in the management of Abbott Medical neurostimulation systems.

Summary of Safety and Clinical Performance

A summary of the safety and clinical performance for this device is available at https://ec.europa.eu/tools/eudamed. Search for the device using the Global Trade Item Number (GTIN; also known as UDI) provided on the Information screen of the clinician programmer application. This is the SSCP location after the launch of the European Database on Medical Devices/Eudamed.

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.

Incident Reporting

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.

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 medical.abbott/manuals). For more information about MR Conditional products, visit the Abbott Medical product information page at neuromodulation.abbott/MRI-ready.

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: For nontherapy-related warnings regarding the St. Jude Medical™ Clinician Programmer, refer to the user guide for the provided Apple‡ iOS‡ device available at support.apple.com/manuals.

Electrosurgery. To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. Before using an electrosurgery device, place the neurostimulator in Surgery Mode using the patient controller app or clinician programmer app. Confirm the neurostimulation system is functioning correctly after the procedure.

During implant procedures, if electrosurgery devices must be used, take the following actions:

- Use bipolar electrosurgery only.
- Complete any electrosurgery procedures before connecting the leads or extensions to the neurostimulator.
- Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible.
- Set the electrosurgery device to the lowest possible energy setting.
- Confirm that the neurostimulation system is functioning correctly during the implant procedure and before closing the neurostimulator pocket.

System components. The use of components not approved for use by Abbott Medical 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.

Precautions

The following precautions apply to these components.

NOTE: For nontherapy-related precautions for the St. Jude Medical™ Clinician Programmer, refer to the user guide for the provided Apple‡ iOS‡ device available at support.apple.com/manuals.

Device Precautions

Nonsterile device. The medical device system comprised of the programmer and other Abbott 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 Abbott 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. The equipment is not serviceable by the customer. To prevent injury or damage to the system, do not modify the equipment. If needed, return the equipment to Abbott Medical for service.

Programmer use. Allow only authorized use of the clinician programmer to avoid any programming changes that may injure a patient.

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). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system or damage system components. 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, radiofrequency identification (RFID) devices, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Wireless use restrictions. In some environments, the use of wireless functions (for example, Bluetooth® wireless technology) may be restricted. Such restrictions may apply aboard airplanes, 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 application (app) (Model 3874) interfaces with Abbott 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.
- 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

The clinician programmer is an Apple‡ iOS‡ device provided by Abbott Medical.

Before you begin, be sure you are familiar with how to perform these basic operational functions on the clinician programmer.

- Turning the clinician programmer on and off
- Placing the clinician programmer in sleep mode
- Waking the clinician programmer from sleep mode
- Locking and unlocking the clinician programmer

- Using touchscreen functions such as tap and screen swipe actions
- Returning to the Home screen

  NOTE: For nontherapy-related information on how to use the clinician programmer, refer to the user guide for the provided Apple‡ iOS‡ device available at support.apple.com/manuals.

Getting Started

This section contains information about navigating the clinician programmer app Home screen and instructions for pairing and connecting the clinician programmer to a generator.

Downloading the Clinician Programmer App

NOTE:

- The clinician programmer app is compatible with the Apple‡ iPad‡ mobile digital device provided by Abbott Medical. The patient controller app is compatible with an Apple iOS‡ mobile digital device (either a device provided by Abbott Medical or a compatible personal Apple iOS device).
- Install the apps well before you need to use them in case you encounter network or server issues.
- Do not install additional applications on the clinician programmer. Contact Abbott Medical before upgrading the iOS software on your device. After upgrading, make sure you download the latest clinician programmer app from the Abbott App Store.

The following steps provide instruction for downloading the clinician programmer app. For instructions on downloading the patient controller app, see the user's guide.

1. Make sure the device is turned on and connected to the internet.

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. Follow the onscreen instructions.
4. When prompted, enter the Group ID.

   NOTE: The Group ID varies depending on where the device is used. See Appendix A (page 63) for the Group ID for your location.

5. Enter your Abbott Medical username and passcode.
   You may wait a minute or longer while the device connects to the server.
6. Tap **Install** on the Install Profile screen.
7. Tap **Install** when prompted to Install Profile.
8. Tap **Install** on the Mobile Device Management Warning screen.
9. Tap **Trust** on the Remote Management screen.
10. Tap **Done** on the Profile Installed screen.
11. Exit your web browser when you reach the Enrollment Complete screen.
    The app icon automatically appears on the clinician programmer Home screen, though it may take a few minutes.

If the app icon does not appear after a few minutes:

1. Tap  on the clinician programmer 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 clinician programmer Home screen.

Navigating the Home Screen

When you launch the clinician programmer app, the clinician programmer app Home screen appears. From this 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. Demonstration Mode provides representative functionality for the clinician programmer app, including creating programs and adjusting parameter limits within available combinations.
- Tap ⓘ to open the Information popover where you can view clinician and programmer information (including the clinician programmer app model number and software version), as well as create and email a programmer log (see “Troubleshooting” (page 55) for instructions).
  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.

- The clinician programmer app times out after 30 minutes of inactivity; however, if you navigate away from the app, 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 10 seconds, and then move the magnet away from the generator.
- You cannot pair the generator to the clinician programmer if the generator is currently communicating with the patient controller. See "Troubleshooting" (page 55) for instructions on ending the session early.
- Before the app can establish communication with the IPG, a prompt may display requesting the user to allow Bluetooth® wireless communication access. Tap **OK** to allow access. Otherwise, the application will be unable to communicate with the generator. Visit support.apple.com for more information.

1. Place the magnet perpendicular to the generator for 10 seconds, and then move the magnet away from the generator.

   If pairing with an External Pulse Generator (EPG), the indicator light on the generator will start flashing.

2. Tap the clinician programmer app.

   The clinician programmer app launches.

3. Tap **Generators** on the clinician programmer app Home screen.

   The Select Generator popover opens.

4. Select an available generator. A white unlock icon is displayed over the generator if the generator is ready to pair.

   If the "No Supported Generators Found" message displays, tap ↻ to search for available generators again and refresh the generator list.

5. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.
6. 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, and then move the magnet away from the generator.

   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 +.

   The Add Generator screen opens.

4. Tap an available generator in the “Select a Generator…” list.

   If the “No Generators Found” message displays, tap ↻ to search for available generators again and refresh the generator list.

5. Enter the pin code displayed on the screen in the Bluetooth Pairing Request dialog box.

6. 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. To delete a generator from the patient controller app:

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 Abbott representative for more information.
- Do not navigate away from the clinician programmer app while you are in a programming session. Enabling Do Not Disturb mode prior to your programming will prevent interruption from occurring during a programming session. Find 'Do Not Disturb' instructions from Apple, which are located at support.apple.com by typing "Do Not Disturb" in the Search Support box.
- Place the IPG into Surgery Mode before entering the operating room. While in the operating room, leave the IPG in Surgery Mode unless you are actively programming. See "Viewing Generator Details" (page 42) for information about placing a generator into Surgery Mode.

Navigating the Program Screen

The Program screen opens once you successfully connect to a generator. See "Switching Between Tonic Mode and Burst Mode" (page 22) 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 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Patient Information button (at top of screen)	Tap to view or edit patient information.
	Generator Icon (at top of screen)	Tap to view generator information.
Revert	Revert button	Tap to revert to the last saved program settings.
	Add/Copy Program button	Tap to add or copy a program.
Program 1	Program Name button	Tap to view and edit the list of available programs.
	Manage Programs button (at top center of screen)	Tap to view, select, or delete the programs on the generator communicating with the clinician programmer app.
Done	Done button	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.

Table 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Add Area or Pulse button	Tap to add an area or pulse to the program.
	Area Options button	Tap to edit a name, delete an area, and balance. (Tonic only)
	Minus button	Tap to decrease the number of pulses. (BurstDR™ stimulation only)
Edit	Edit button	Tap to edit the lead diagram settings.
	Electrode button	Tap to change the electrode settings.
	Up button	Shift the electrode polarities up. This feature is only available with certain lead types.
	Down button	Shift the electrode polarities down. This feature is only available with certain lead types.
	Up button	Use the MultiSteering™ programming feature to steer the electrical field up.

Table 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Down button	Use the MultiSteering programming feature to steer the electrical field down.
	Left button	Use the MultiSteering programming feature to steer the electrical field left.
	Right button	Use the MultiSteering programming feature to steer the electrical field right.
	Generator anode button (at bottom of the lead configuration screen)	Tap to change the generator to anode. This option removes anodes from the leads. (IPG only)
	Program Options button (at bottom of screen)	Tap to change the active program options.
	Stop stimulation button	Tap to stop stimulation.
	Clear button	Tap to clear the contents of a text field.
	Delete button control (visible in popovers)	Tap to reveal or hide the Delete button.

Table 1. Program screen descriptions

Button or Icon	Button or Icon Name	Description
	Reset button	Tap to reset to the most recently saved settings.
Back	Back button	Tap to save changes and return to the previous screen or popover.
Cancel	Cancel button	Tap to discard changes and return to the previous screen or popover.
	Share report button	Tap to email or print the report.

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:

1. Tap **Generators** on the clinician programmer app 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" (page 45) 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:

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. Tap **Edit** and then edit the default patient information to create a new patient.
4. Tap **Done** to return to the Patient popover.

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:

1. From the Program screen, tap ⓘ. The Patient popover opens.
2. Select **Edit**.
3. 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.
4. Tap a patient name to select that patient.
5. Tap **Done**. The Reassign Generator popover opens.
6. Tap **Reassign** to reassign the generator and close the popover.

Selecting the Lead Configuration

NOTE: If a lead model is an approved MR Conditional component, an MR Conditional icon (MR) 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:

1. Tap **Edit** in the lead diagram area on the Program screen.
2. Tap +.
   The Lead Options popover opens.
3. Tap **Model**.

The Model popover opens.

From the Model 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.

4. Select **Yes** or **No** if you are using a lead extension.

   This popover only opens if you select an MR Conditional lead.

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

To select the patient's lead configuration:

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. Additionally, the perception and comfort amplitude values clear on tonic programs or the target amplitude value clears on BurstDR™ stimulation programs, as well as any previous area impedance results.

To configure electrode polarities:

- 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 BurstDR™ stimulation programming mode on the Program screen.

NOTE:

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

1. On the Program screen, tap ☰ to open the Program Options popover.
2. Tap the Burst Mode toggle button to switch between tonic stimulation and BurstDR stimulation.
   - Off (toggle button to the left, white), means tonic stimulation is selected
   - On (toggle button to the right, blue), means BurstDR stimulation is selected
3. Tap **Change** to confirm switching the program mode.

   When burst mode is active, the Program screen displays the features for BurstDR stimulation 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 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 .
- When the generator reaches its energy or charge density limit, a notification appears. Try reducing the frequency, pulse width, and amplitude.
- When the generator reaches its output limit, the parameter boxes turn yellow. You may still increase amplitude but cannot save the program. To reduce the generator output, try reducing the amplitude or pulse width or setting additional anodes or cathodes on the lead configuration.
- If you change electrode polarities after setting the amplitude value, the amplitude value clears.

To adjust amplitude:

- 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.
- Tap a toggle button in the Areas section on the Program screen to turn stimulation on.

  NOTE: When creating a tonic program, you may choose between two minimum step sizes (0.05 or 0.10 mA), which determine the maximum available amplitude (12.75 or 25.5 mA, respectively).

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: When you change the frequency value using the Frequency box, stimulation turns off and the amplitude value clears.

  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.
- 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:

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.
   - If all stimulation areas are on when you end the programming session, stimulation ramps to the comfort amplitude. If any stimulation area is off when you end the session, stimulation for all areas is turned off.

Adjusting Frequency for Burst Programs

BurstDR™ stimulation 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 BurstDR stimulation programs, the Burst Rate and Intra-burst boxes on the Program screen display system default values.

To change the frequency values for a BurstDR stimulation 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 BurstDR™ stimulation 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.
- If you change electrode polarities after you have set the value for target amplitude, the target amplitude value will clear.
- 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:

- 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 BurstDR™ stimulation 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:

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 BurstDR™ stimulation 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.

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:

1. Tap the Patient Controller box to open the Patient Controller popover.
2. Tap the Use Custom Settings toggle button 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.

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 BurstDR™ stimulation programs. The stimulation map also appears on the user's patient controller app.

To create a stimulation map:

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.

To measure impedance for the programmed electrode array:

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.
   a. Tap **Start** to start an impedance check on all electrodes. Stimulation turns off during the impedance check.

b. Tap **Dismiss** to view the impedance results for each electrode or **View Report** to view the System Impedance report.

c. After tapping Dismiss, tap an electrode to open the popover with the impedance results for that electrode.

d. Tap **Done** to exit the Full System impedance view.

NOTE: If electrodes on the Program screen turn yellow, your impedance measurement is high or low. See “Troubleshooting” (page 55) for more information.

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.

To turn on impedance logging:

1. Tap **Impedance Log** on the generator popover. The impedance log popover opens.
2. Tap the impedance log toggle button.

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:

1. On the Program screen, tap +.
2. Tap **Add New Program** in the popover. A new program is automatically named according to the next available number.
3. Set the desired parameters.

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

Changing the Active Program

To change the active program:

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:

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:

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 **Back** to save changes and return to the Programs popover.
7. Tap **Done** to save changes and outside the popover to close the popover.

Deleting a Selected Program

To delete a program:

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 “Editing an Area in a Program” (page 27) or “Decreasing the Number of Burst Pulses” (page 28) for more information.

Modifying Program Options

You may modify the active program options. To access the options:

- Tap ☰ at the bottom of the Program screen to open the Program Options screen. From the Program Options screen, you may perform the following actions:
  - Set the burst mode (visible if Burst Mode is unlocked).
  - Set the dosage.
  - Set the microdose on and off times.
  - Set the step size increment. (Tonic only)
  - Set the sleep on time. (EPG only)
  - Set the magnet mode.
  - Set the ramp time for sleep (EPG only) or continuous dosage.

To modify program options:

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 Dosage

The dosage setting controls the delivery of stimulation. The following table provides definitions of the dosage options that may be available.

Table 2. Definitions of Dosage Options

Dosage	Definition
Continuous	Stimulation is delivered continuously while the generator is on and the program is running.
Microdose	Stimulation is on for a programmed amount of time (on time) and off for a programmed amount of time (off time). Stimulation alternates between on and off states until the generator is turned off or the program is stopped.
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 dosage:

1. Tap **Dosage** on the Program Options screen.
2. Tap the desired dosage.
   - If you tap Microdose, On Time and Off Time becomes available on the Program Options popover.
   - 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:

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** to return to the Program Options screen or outside the popover to save any changes and return to the Program screen.

NOTE: You can set the microdose on and off 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 sleep on 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:

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 **Done** or outside the popover to save any changes and close the popover.

To Set the Magnet Mode

The magnet mode setting controls how the generator responds when it senses a magnet. The default magnet mode is Turns Stimulation On/Off.

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 **Only Turns Stimulation Off** to turn generator stimulation off when the generator senses a magnet.
- Tap **Done** or outside the popover to save any changes and close the popover.

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 BurstDR™ stimulation programs and is only available for sleep (EPG only) or continuous dosage. 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:

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 **Done** or outside the popover to save any changes and close the popover.

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:

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.
   - 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 and exit the session, programs are automatically saved and a Session report opens. You may manually exit the programming session by performing the following actions:

1. 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.
- During intraoperative testing, you do not need to save the program. To exit an intraoperative testing session and return to the clinician programmer app Home screen, tap **Done** and then **End Session** on the Program screen. When asked by the system if you want to discard the changes, tap **Yes**.

- If any parameters of an area 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.
- If all stimulation areas are on when you end the session, stimulation ramps to the comfort amplitude. If any stimulation area is off when you end the session, stimulation for all areas is turned off.

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 rename a program on the list:

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 or view the program settings:

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:

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. Tap at the top of the screen to open the Generator popover. 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.
- View and change the generator name from the Name popover. This name is displayed on the generators list for both the clinician and patient.

- View and change the implant date on the Implant Date popover (IPG only).
- Set an IPG to Surgery Mode.
- 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.)
- View how long stimulation has been on.
- View the generator battery status. See “Checking the Generator Battery Status” (page 51) for more information.
- Turn impedance logging on or off. See “Measuring Impedance” (page 29) for more information (IPG only).
- Email a generator log, which contains information such as how stimulation was used, that may help when troubleshooting.

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 email a generator log:

1. Tap **Generator Log** on the Generator popover.
2. Tap **Email Basic Generator Log** or **Email Complete Generator Log** as directed.

   The popover closes. The “Exporting Log File” message displays while the system is generating the log file and email.
3. Enter the email address.

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

To set an IPG into Surgery Mode:

1. Tap **Surgery Mode** on the Generator popover. The Surgery Mode popover opens.
2. Tap the **Surgery Mode** toggle button.

   Stimulation stops and the patient may undergo their surgical procedure.

   NOTE: If Surgery Mode is on, you will not be able to perform any programming actions. The IPG remains in Surgery Mode until you tap **Exit Surgery Mode** on the screen.

To set an applicable IPG into MRI mode:

1. Tap **MRI Mode** on the Generator popover. The MRI Mode popover opens.
2. Tap the **MRI Mode** toggle button.

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.

   CAUTION: Do not delete the paired Bluetooth® wireless connection between the IPG and the clinician programmer (under Settings > Bluetooth on the clinician programmer) while the system is in MRI mode. Doing so will prevent the system from disabling MRI mode, which may prevent therapy from being turned on again.

   CAUTION: Carefully monitor which clinician programmer is paired with an IPG that is in MRI mode. It is not possible to create a new pairing with an IPG while it is in MRI mode, so a previously paired clinician programmer is necessary to disable 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. See “Troubleshooting” (page 55) for more information.
   - If MRI mode is on, you will not be able to perform any programming actions. The IPG remains in MRI Mode until you tap **Exit MRI Mode** on the screen.

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 3. Buttons and icons on the patient records screens

Button or Icon	Button or Icon Name	Action
	Clinician programmer Home screen button	Tap to go to the clinician programmer app Home screen.
Edit	Edit patient list button	Tap to edit the patient list.
	Add patient button	Tap to add a patient.
	Patient information button	Tap to view patient information.
	Delete patient button	Tap to delete the patient.
Search	Name Search field	Tap to search for a patient name.
Patient name	Patient name in patient list	Tap to open the patient overview for the selected patient.

Table 3. Buttons and icons on the patient records screens

Button or Icon	Button or Icon Name	Action
	Delete generator button	Tap to delete the generator.
	Generator Backup button	Tap to email the backup file. (Only available when a backup file exists.)
Sessions	Sessions	Tap to view the session history list.
Diagnostics	Diagnostics	Tap to view the diagnostics history list.
	Session detail button	Tap to open the selected session summary.
	Clear button	Tap to clear the contents of a text field.
Cancel	Cancel button	Tap to cancel the action and close the popover.
	Share report button	Tap to email or print the report.
	Email button	Tap to email the report.
	Print button	Tap to print the report.

Table 3. Buttons and icons on the patient records screens

Button or Icon	Button or Icon Name	Action
	Email XML button	Tap to launch Email App and attach XML file.

Adding a Patient

To add a patient:

1. From the patient records screen, tap  . 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:

1. From the Program screen, tap  . 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:

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**.

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 “Measuring Impedance” (page 29).

- 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.
  - Configure mail support before using the email report functionality.

To generate a Session report:

1. Tap **Sessions** on the right 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:

1. Tap **Diagnostics** on the right 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

Refer to the IPG and EPG information below for instructions on viewing the generator battery status. 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: You may also receive low battery warnings regarding the clinician programmer, so make sure to read the warning before dismissing.

To view the IPG battery status:

You can view the IPG generator battery status in the Generator popover. When the IPG status is good,  is displayed; and when the battery is approaching the end of service,  is displayed. The battery voltage reading is provided next to the status icon until the battery voltage reaches the set elective replacement indication voltage limit. After the battery voltage reaches this limit, the reading only shows the battery voltage is less than the set limit.

NOTE:

- The IPG battery status is calculated from recent voltage measurements. If usage habits change for a period of time, this may affect the battery status. The IPG battery status is available one day after first using the clinician programmer app to program the IPG. For more information, as well as information about battery longevity estimates, refer to the clinician's manual for the generator.
- When the IPG battery is approaching the end of service a warning pops up on your clinician programmer app.

To view the EPG battery status:

You can view the EPG generator battery status in the generator icon on the Program screen and in the Generator popover. The Generator popover displays the remaining life for the EPG battery (the figure below shows the EPG battery indicator progression).

Figure 1. EPG battery indicator progression

NOTE:

- When the remaining EPG battery charge reaches 2 or 1, a warning pops up on your clinician programmer app.
- When the EPG battery is too low to support stimulation (0), you may not be able to initiate a programming session with the clinician programmer. Replace the generator batteries to connect and communicate with the generator.

- When the EPG battery is too low to support stimulation (0), generator stimulation automatically turns off and the clinician programmer app ends the programming session. Replace the generator batteries to connect and communicate with the generator.

  WARNING: Turn stimulation off before removing the batteries. Removing the batteries while stimulation is on could cause unintended stimulation.

Maintaining the Clinician Programmer

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

Checking the Clinician Programmer Battery Status

Be sure to monitor 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 user guide for the provided Apple iOS‡ device available at support.apple.com/manuals.

Caring for the Clinician Programmer

For information on how to care for the clinician programmer, refer to the user guide for the provided Apple‡ iOS‡ device available at support.apple.com/manuals.

Cybersecurity

To protect the devices, products, and systems that connect patients to healthcare professionals and institutions, Abbott takes a broad and deep approach to ensuring safety, privacy, and security. Visit the information page available at www.NMCybersecurity.Abbott to learn more about the Abbott Medical neuromodulation cybersecurity program. Periodically, Abbott may update this website with important messages related to the cybersecurity of your patient device.

IT Security Measures

To keep patient data and communications secure, the system includes the following IT security measures.

- Use of a device passcode is required to access the mobile device. Use unique numeric sequences that you can remember easily.
- Data at rest on the mobile device is stored in encrypted form.
- Backups may be created using the iTunes‡ software with instructions from Apple, which are located at support.apple.com by typing “backup” or “back up” in the Search Support box.
- Backups created using iTunes are encrypted.

In addition, users should adhere to the following guidelines when using the system:

- Do not use the application if the operating system is compromised (for example, jailbroken).
- Do not share your Apple‡ ID login information or device passcode.
- Do not allow other users to access the mobile device.
- Installation of apps that are not approved by Abbott Medical for use in the system is restricted.

- Secure networks to which the Apple device will connect with a Wi-Fi‡ password or other similar security measures.
- Connect only to trusted secured networks.
- If the Apple device is lost or stolen, contact your Abbott Medical representative to remotely erase your patient information from the device. Use the Apple instructions at support.apple.com by typing “lost” or “stolen” in the Search Support box to disable or erase your device.
- If you receive a “Device Not Secure” notification in the App, contact Abbott Medical.
- Install iOS‡ software upgrades on your device as they are made available by Apple, after contacting Abbott Medical to ensure compatibility with the Clinician Programmer App.
- Install Clinician Programmer app updates as they are released.

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 “Viewing Generator Details” (page 42) for instructions about creating a generator log and the steps below for instructions about creating a programmer log.

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

To create and email a programmer log:

1. On the clinician programmer app Home screen, tap ⓘ to open the Information popover.

2. Tap **Email Programmer Log**.

   The popover closes. An “Exporting Logs” system message is displayed while the system is generating the log file and email.

3. Enter the email address.

   NOTE: Configure mail support before using the Email Programmer Log functionality.

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 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Clinician programmer has no power or has lost power.	Clinician programmer’s battery is drained.	Recharge the battery using the charger.
	Clinician programmer is damaged or malfunctioning.	Replace the clinician programmer.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Clinician programmer will not charge.	Charger is disconnected from the clinician programmer.	Connect the charger to the clinician programmer.
	Correct plug adapter (voltage converter) is not connected to the charger.	Connect the appropriate plug adapter (voltage converter) to the charger.
	Charger is defective.	Replace the charger.
	Clinician programmer is damaged or malfunctioning.	Replace the clinician programmer.
Nothing is displayed on the screen.	Clinician programmer is off or has timed out.	Turn on the clinician programmer.
	Clinician programmer's battery is drained.	Recharge the battery using the charger.
	Screen is damaged or malfunctioning.	If the clinician programmer appears to be powered on but without display, the screen may be defective. Contact Technical Support.
Clinician programmer will	Clinician programmer has locked up.	Perform a soft reset by turning the clinician programmer off and back on.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
not respond to input.	Touchscreen interface is damaged or malfunctioning.	Replace the clinician programmer.
	Clinician programmer battery is drained.	Charge the clinician programmer battery.
	Bluetooth® wireless connection is not strong or turned off.	Decrease the distance between the devices. Move away from sources of interference such as appliances, Wi-Fi‡ routers, or electrical equipment.
		Move the devices so they share line of sight.
		Do not operate other wireless devices at the same time.
		Disconnect any Bluetooth® wireless media accessories (such as headphones or speakers).
		Wait a few minutes and try connecting again.
		Turn on Bluetooth wireless connection if connectivity is disabled:

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		Return to the clinician programmer Home screen, tap **Settings**, tap **Bluetooth**, and then tap the **Bluetooth** toggle button.
	Clinician programmer is damaged or malfunctioning.	Replace the clinician programmer.
Patient is not receiving stimulation.	Stimulation is off.	Turn on stimulation using the patient controller app.
	Generator battery is low and stimulation shut off.	Replace the EPG batteries. For more information, refer to the clinician's manual for the generator.
	Lead is damaged or has become disconnected.	Check impedance on the lead using the clinician programmer app. If impedance is high, 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. See "Measuring Impedance" (page 29) for more information.
	Generator is damaged or malfunctioning.	Replace the generator. Contact Technical Support.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
Parameter boxes on the Program screen turn yellow.	Generator has reached its output limit and is in overhead.	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.
	Lead is damaged or has become disconnected.	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. See "Measuring Impedance" (page 29) for more information.
Cannot locate clinician programmer app.	Clinician programmer app is not on clinician programmer Home screen.	Swipe through screens from the clinician programmer Home screen to locate app. Search for the app using the iOS‡ search function.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
		Re-install the app. See “Downloading the Clinician Programmer App” (page 7).
Surgery Mode is Not Available is displayed.	The IPG has the maximum number of allowed programs.	Delete a program and try setting Surgery Mode again.
Cannot place the IPG into Surgery Mode.	The IPG is not connected to the clinician programmer.	Try connecting to the IPG again. If the problem persists, contact Technical Support.
MRI is Not Permitted is displayed instead of the MRI Mode option on the Generator popover.	A part of the implanted system is not MR Conditional.	Confirm the implanted models of the system. If any implanted part is not MR Conditional, the patient cannot receive an MRI scan.
MRI is Not Advised message appears while trying to set	A problem was detected during the system checks while setting MRI mode.	The IPG is not in MRI mode, and an MRI scan cannot be performed.

Table 4. Possible causes and solutions for potential issues

Problem	Possible Cause	Possible Solution
the IPG to MRI mode.		
Generator software upgrade was not successful.	Generator software upgrade was interrupted.	Try installing the generator software again. If you cannot locate the generator on the clinician programmer app, contact Technical Support.
Cannot locate programs after upgrading generator software.	After installing generator software, the previous program data was lost.	1. On the patient records screen, locate the patient history. 2. Reprogram the patient.

Technical Support

For technical questions and support for your product, use the following information:

- +1 855 478 5833 (toll-free within North America)
- +1 651 756 5833

For additional assistance, call your local Abbott 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 5. Group ID list

Country/Region	Group ID	Country/Region	Group ID
Algeria	PRODEU	Lebanon	PRODLBN
Argentina	PRODLATAM	Luxembourg	PRODEU
Australia	PRODAUSNZ	Malaysia	PRODEU
Austria	PRODEU	Mexico	PRODLATAM
Belgium	PRODEU	Netherlands	PRODEU
Brazil	PRODLATAM	New Zealand	PRODAUSNZ
Canada	PRODCAN	Norway	PRODEU
Chile	PRODLATAM	Panama	PRODLATAM
China	PRODCHN	Peru	PRODLATAM
Colombia	PRODLATAM	Poland	PRODEU
Costa Rica	PRODLATAM	Portugal	PRODEU

Table 5. Group ID list

Country/Region	Group ID	Country/Region	Group ID
Cyprus	PRODEU	Puerto Rico	PRODUSA
Czech Republic	PRODEU	Russia	PRODRUS
Denmark	PRODEU	Saudi Arabia	PRODAPAC
Ecuador	PRODLATAM	Singapore	PRODSGP
Finland	PRODEU	South Africa	PRODEMEA2
France	PRODEU	South Korea	PRODAPAC
Germany	PRODEU	Spain	PRODEU
Greece	PRODEU	Sweden	PRODEU
Hong Kong	PRODAPAC	Switzerland	PRODEU
Iceland	PRODEU	Taiwan	PRODAPAC
India	PRODAPAC	Thailand	PRODAPAC
Ireland	PRODEU	Turkey	PRODEMEA2
Israel	PRODAPAC	UK	PRODEU

Table 5. Group ID list

Country/Region	Group ID	Country/Region	Group ID
Italy	PRODEU	US	PRODUSA
Japan	PRODJPN	Country Not Listed	PRODOTHER

Appendix B: Regulatory Statements

NOTE: For Regulatory Statements regarding the clinician programmer, refer to the user guide for the provided Apple‡ iOS‡ device available at support.apple.com/manuals; or, on the clinician programmer Home screen, tap **Settings** > **General** > **Legal & Regulatory**.

Appendix C: Symbols and Definitions

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

NOTE: For symbols and definitions for the clinician programmer, refer to the user guide for the provided Apple‡ iOS‡ device available at support.apple.com/manuals; or, on the clinician programmer Home screen, tap **Settings > General > Legal & Regulatory**.

Table 6. Symbols and definitions

Symbol	Definition
	Caution
	Refer to instruction manual/booklet
	Consult instructions for use
 medical.abbott/manuals	Follow instructions for use on this website
	Type BF Applied Part
	MR Conditional NOTE: Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within the defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field, and the

Table 6. Symbols and definitions

Symbol	Definition
	radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.
	MR Unsafe NOTE: Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Non-ionizing electromagnetic radiation
	Keep dry; keep away from rain
IP22	Ingress protection rating for a device that is protected from the intrusion of solid foreign objects as small as 12.5 mm in diameter and is protected from vertically dripping water when the device is tilted at an angle up to 15 degrees
	Use-by date

Table 6. Symbols and definitions

Symbol	Definition
	Date of manufacture
	Catalog number NOTE: This symbol also refers to the model number.
	Manufacturing facility
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

Table 6. Symbols and definitions

Symbol	Definition
	Manufacturer
	Do not use if package is damaged
	Packaging unit
	Programmer
	Accessories
	Serial number
	Batch code
	Unique Device Identification

Table 6. Symbols and definitions

Symbol	Definition
MD	Medical Device
℞ ONLY	Prescription use only
	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Abbott Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Abbott Medical.
EC REP	Authorized representative in the European Community
	Importer

Table 6. Symbols and definitions

Symbol	Definition
CE 2797	European conformity, affixed in accordance with the relevant provisions of European Council Regulation 2017/745 (NB 2797). Hereby, Abbott Medical declares that this device is in compliance with the relevant provisions of this regulation.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law

Appendix D: CE Mark Date

The following table lists the year in which the CE mark was awarded by model number.

Table 7. Year in which CE mark was awarded

Model	Year
3874	2015

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