directSTIM™ Deep Brain Stimulation System
Clinician Programming Manual

Clinician Programmer
Model 12200

Trial Stimulator
Model 12400

CE 0344

℞ ONLY 2019

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directSTIM™ is a trademark of Aleva Neurotherapeutics SA.

Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, and related information.

Limited warranty packaged separately.

FCC Information (US Only)

The following is communications regulation information about the directSTIM Clinician Programmer and Trial Stimulator:

- Clinician Programmer FCC ID: 2ABU84500 contains FCC ID: U9R-W2CBW003
- External Pulse Generator (Trial Stimulator) FCC ID: 2ABU84300

These devices comply with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) These devices may not cause harmful interference, and (2) These devices must accept any interference received including interference that may cause undesired operation.

Important: Changes and modifications to the products not authorized by Aleva could void the FCC certification and negate your authority to operate these products.

Packaging Symbols Glossary

Symbol	Explanation
	Title: Catalog Number **Standard:** ISO 15223-1 **Reference Number:** 5.1.6[1] **Description:** Indicates the manufacturer's catalog number so that the medical device can be identified.
	Title: Serial Number **Standard:** ISO 15223-1 **Reference Number:** 5.1.7[1] **Description:** Indicates the manufacturer's serial number so that the medical device can be identified.
	Title: Date of Manufacture **Standard:** ISO 15223-1 **Reference Number:** 5.1.3[1] **Description:** Indicates the date when the medical device was manufactured.
	Title: Manufacturer **Standard:** ISO 15223-1 **Reference Number:** 5.1.1[1] **Description:** Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC and 93/42/EEC.
	Title: Packaging unit **Standard:** ISO 7000:2014 **Reference Number:** 2794[2] **Description:** Indicates the number of pieces in the package.
	Title: Consult instructions for use **Standard:** ISO 15223-1 **Reference Number:** 5.4.4[1] **Description:** Indicates the need for the user to consult the instructions for use.
	Title: Caution **Standard:** ISO 15223-1 **Reference Number:** 5.4.4[1] **Description:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Title: Do not use if package is damaged **Standard:** ISO 15223-1 **Reference Number:** 5.2.8[1] **Description:** Indicates a medical device that should not be used if the package has been damaged or opened.
	Title: Keep dry **Standard:** ISO 15223-1 **Reference Number:** 5.3.4[1] **Description:** Indicates a medical device that needs to be protected from moisture.
	Title: Temperature limit **Standard:** ISO 15223-1 **Reference Number:** 5.3.7[1] **Description:** Indicates the temperature limits to which the medical device can be safely exposed.
	Title: Humidity limitation **Standard:** ISO 15223-1 **Reference Number:** 5.3.8[1] **Description:** Indicates the range of humidity to which the medical device can be safely exposed.
	Title: Atmospheric Pressure limitation **Standard:** ISO 15223-1 **Reference Number:** 5.3.9[1] **Description:** Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Title: Fragile, handle with care **Standard:** ISO 15223-1 **Reference Number:** 5.3.1[1] **Description:** Indicates a medical device that can be broken or damaged if not handled carefully.
	Title: MR Unsafe **Standard:** ASTM F2503-13 **Reference Number:** 7.4.10[3] **Description:** MR is contraindicated, no testing was performed yet.

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Symbol	Explanation
	Title: Non-ionizing electromagnetic radiation **Standard:** IEC/TR 60878 **Reference Number:** 5140[4] **Description:** To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems, e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	Title: Class II equipment **Standard:** IEC/TR 60878 **Reference Number:** 5172[4] **Description:** To identify equipment meeting the safety requirements specified for class II equipment according to IEC 61140.
	Title: Symbol for the marking on EEE **Standard:** BS EN 50419:2006[5] **Description:** Indicates that when end user wishes to discard this product it must be sent to separate collection facilities for recovery and recycling in the EU.
	Title: Type BF Applied Part **Standard:** ISO 7000/IEC 60417 **Reference Number:** 5333[2] **Description:** To identify a type BF applied part complying with IEC 60601.
	Title: Rx Only **Standard:** 21 CFR Part 801.109 paragraph (b)(1) **Description:** Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Title: European Conformity **Directive:** 90/385/EEC Annex IX **Description:** Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

1. ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
2. ISO 7000:2014 Graphical symbols for use on equipment – Registered symbols
3. ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
4. IEC/TR 60878:2015 Graphical Symbols for Electrical Equipment in Medical Practice
5. BS EN 50419:2006 Marking of Electrical Equipment in accordance with Article 11 of Directive 2012/19/EU (WEEEII)

Terminology

This manual and the Clinician Programmer use the following terms interchangeably:

- *trial stimulator* and *External Pulse Generator (EPG)*
- *implantable stimulator* and *Implantable Pulse Generator (IPG)*
- *stimulator* to represent both a trial stimulator and an implantable stimulator

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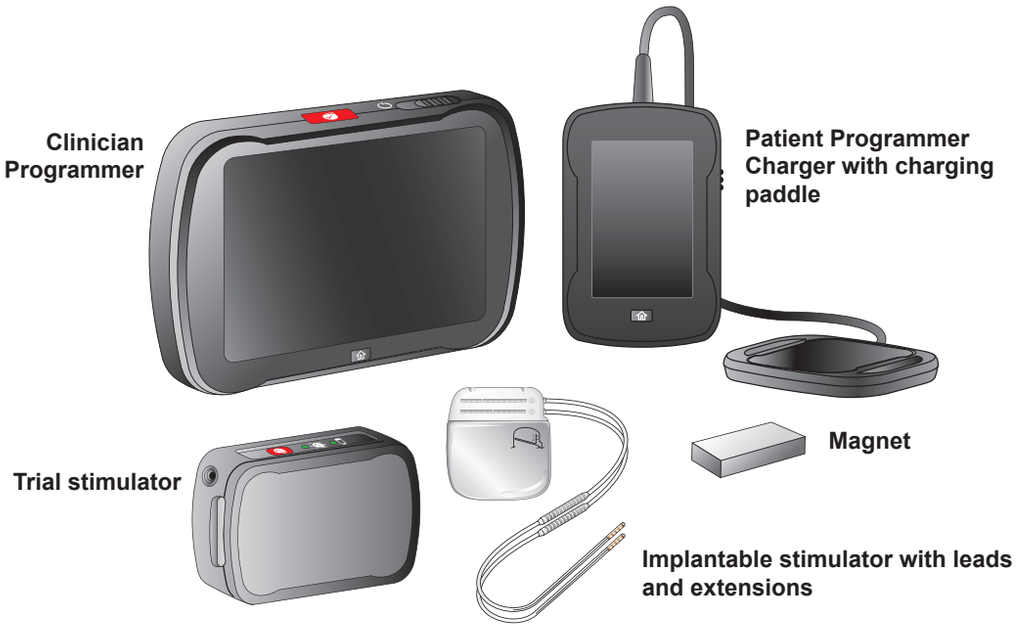
1. About the Clinician Programmer

The Aleva directSTIM™ Clinician Programmer Model 12200 is part of the directSTIM Deep Brain Stimulation (DBS) System. The directSTIM DBS System is a rechargeable, 2 x 12-electrode lead, deep brain stimulation system:



The directSTIM DBS System can be implanted to deliver unilateral or bilateral stimulation, with the most common implantation for bilateral stimulation. For bilateral stimulation, two leads and two extensions are connected to an implantable stimulator. For unilateral stimulation, one lead and one extension are connected to an implantable stimulator.

For optional intraoperative testing during lead placement, a trial stimulator provides stimulation by emulating the implantable stimulator. The clinician programs the directSTIM DBS System using the Clinician Programmer. The patient uses the Patient Programmer Charger to control stimulation and charge the implantable stimulator. The patient can also use the magnet to turn stimulation on or off.

Using the Clinician Programmer

The Clinician Programmer is a hand-held, rechargeable device used to program stimulation delivered by a stimulator. Clinicians can use any Clinician Programmer to communicate with a patient's directSTIM DBS System.

The main tasks a clinician performs with the Clinician Programmer are:

- Configuring the directSTIM DBS System component connections.
- Adding and adjusting programs for patients.
- Synchronizing patient information (including programs) between the Clinician Programmer and a stimulator.
- Pairing one or more Patient Programmer Chargers to a stimulator.

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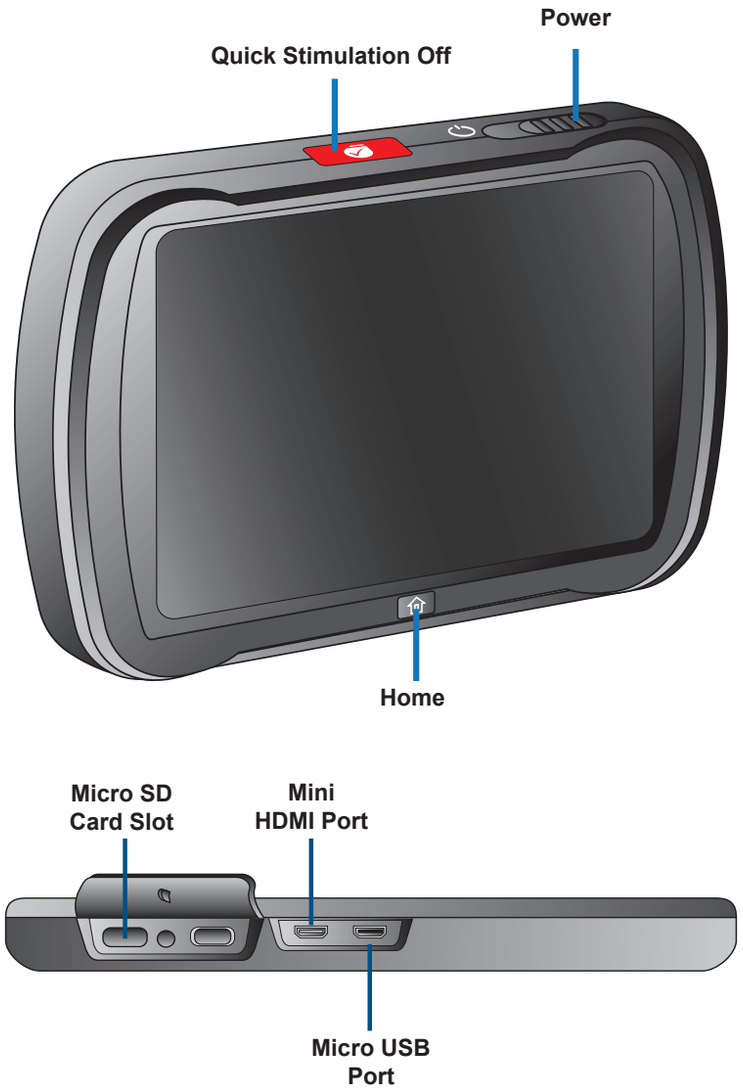

	Press to stop stimulation for the selected patient. The Clinician Programmer queries and displays a list of stimulators in range, if a patient is not selected.
Power	Slide and hold to turn the Clinician Programmer on and off. Refer to *Turning the Clinician Programmer On and Off on page 3.*
	Tap once to return to the patient list. Tap a second time to log out.
Micro SD Card Slot	Contains the SD card required for operation. Do not use the card from another device, including another Clinician Programmer. Other devices cannot access the information on the card.
Mini HDMI Port	Use with a commercially available cable to connect to an IEC 60950-1 certified external monitor for viewing. Control still occurs via the Clinician Programmer, and not through the connected monitor.
Micro USB Port	Use to connect the provided power cord to recharge the Clinician Programmer.

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Turning the Clinician Programmer On and Off

To turn on the Clinician Programmer:

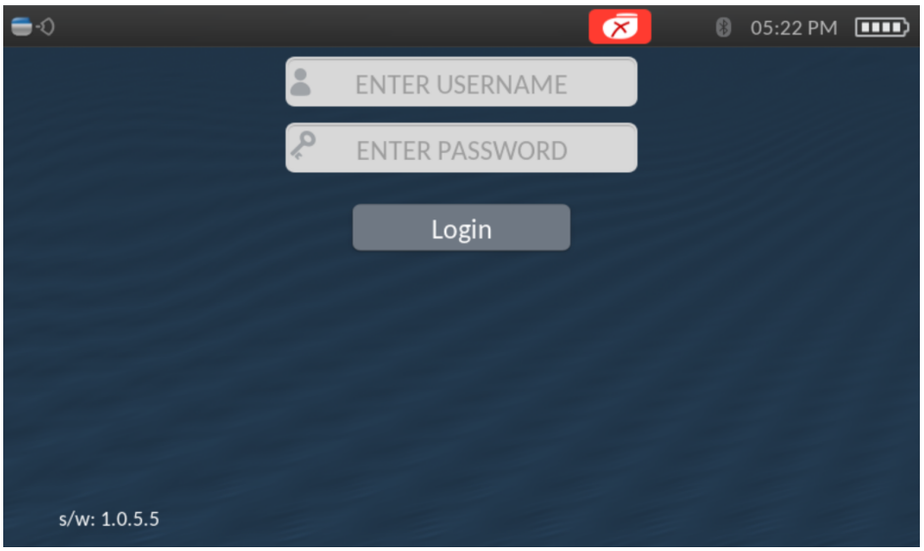
- Slide and hold **Power** for two seconds.

To turn off the Clinician Programmer:

- Slide and hold **Power** for five seconds.

Logging In to the Clinician Programmer

Log in to the Clinician Programmer to access patient information. The initial user name is *admin* and the password is *admin*. To reset the password for the administrator user or create accounts for additional users, refer to *User Administration on page 37*.



Using the Status Bar

The status bar, which displays across the top of each screen, contains status icons for the Clinician Programmer and the patient's stimulator.

Note: All icons on the status bar, except for and , are informational only; they do not result in an action when tapped.

	Tap to manually connect to or disconnect from the stimulator. A dialog with the serial number and model number displays when the Clinician Programmer detects a stimulator.
	Indicates the Clinician Programmer is communicating with the selected patient's stimulator.
	Displays the battery level of the patient's stimulator. Displays EPG for a trial stimulator or IPG for an implantable stimulator. Displays red if the battery is low.
Patient Name	Displays the patient selected from the patient list. **Note:** Verify the patient name in the status bar matches the patient you are treating.
	Tap to stop stimulation for the patient. The Clinician Programmer queries and displays a list of stimulators in range, if a patient is not selected.

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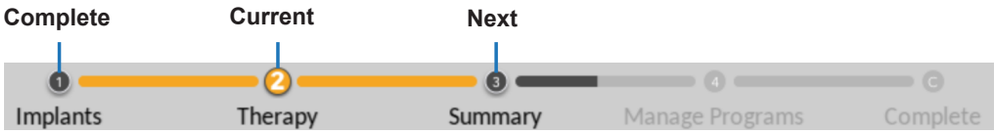
	Illuminates when the Clinician Programmer connects to a printer.
	Displays the battery level of the Clinician Programmer.

Using the Clinician Programmer Workflow

After selecting a patient from the patient list, a workflow displays along the bottom of the screen. The clinician advances through the workflow to configure system components and create, adjust, and manage programs.

Colors in the workflow indicate progression. Black task numbers indicate completed or next tasks. Yellow task numbers indicate the current task. Gray task numbers indicate an uncompleted task. As the clinician completes a task, the bar between the current task and the next task turns yellow.



When a clinician selects a patient from the patient list, the Clinician Programmer automatically advances to the task in progress, or the Manage Programs task if a patient has at least one saved program.

The workflow includes the following tasks:

1 Implants	Add a stimulator, add one or two leads, and configure the lead to stimulator port connections.
2 Therapy	Select electrodes to stimulate, configure stimulation parameters (amplitude, pulse width, and frequency), select stimulation polarity for the leads, and optionally score the beneficial effect and side effect of stimulation.
3 Summary	Save programs. Optionally, define an amplitude range that gives the patient the ability to adjust stimulation with their Patient Programmer Charger.
4 Manage Programs	Synchronize patient information and programs and one or more Patient Programmer Chargers with a stimulator, and start stimulation.
5 Complete	The patient can use the programs.

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Understanding Screen Conventions

Screen elements and controls for configuring programs or delivering test stimulation are color-coded to differentiate between the brain hemispheres. The hemisphere coloring is oriented to the patient's brain while looking at the patient's face. Elements associated with the patient's right hemisphere are blue, and elements associated with the patient's left hemisphere are pink. The following figure shows the color-coded settings and controls for both hemispheres.

Stopping Stimulation

Turn stimulation off with the Clinician Programmer, the Patient Programmer Charger, or the magnet.

Note: If using the Clinician Programmer or Patient Programmer Charger to turn off stimulation, make sure the stimulator is within range (1 meter).

To stop stimulation:

- Press on the top of the Clinician Programmer.

  –or–

  Tap in the status bar of any Clinician Programmer screen.

  –or–

  Tap on the Patient Programmer Charger.

  –or–

  Swipe the magnet over the stimulator. Refer to the Patient System Manual for more information.

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2. Important Safety Information

Warnings

Other Active Implanted Medical Devices. The effects of a Clinician Programmer or Patient Programmer Charger interacting with other active implantable medical devices (eg, pacemakers, defibrillators, implanted spinal cord and peripheral nerve stimulators, deep brain stimulators, implanted infusion pumps, or cochlear implants) are unknown. Do not charge the stimulator, use the Clinician Programmer, or use the Patient Programmer Charger to change program settings when near a person who has an active implanted device. Exercise caution when other implanted devices are operating concurrently with the directSTIM DBS System. Possible effects include sensing problems and unwanted device responses.

Component Modification. Do not modify the power cord. Modifying a directSTIM DBS System component may result in damage to the system, compromised system integrity, or patient harm or injury.

Electromagnetic Interference (EMI). Do not attempt to program near equipment that may generate electromagnetic interference as it may interfere with Clinician Programmer communication. If EMI disrupts programming, move the Clinician Programmer away from the source of EMI. Refer to Information for Prescibers Manual for more information.

Precautions

Component Compatibility. Only use the Clinician Programmer and accessories in the directSTIM DBS System to program the stimulator or trial stimulator, charge the Clinician Programmer, or adjust stimulation. The effects of non-directSTIM DBS System components on a directSTIM DBS System are unknown.

Flammable Atmospheres. Avoid using the Clinician Programmer in flammable or explosive environments (eg, flammable anesthetic mixtures or environments with greater than 25% oxygen). Using a battery-powered device near flammable or explosive environments can produce a spark, which may cause injury.

Power Failures. Power failures (without battery backup) during use will reinitialize the Clinician Programmer. Any unsaved information is lost; saved information is retained.

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3. Managing Patients

The clinician adds and manages patient information using the Clinician Programmer. As the clinician adds patients to the Clinician Programmer and updates existing patient demographics and system components, the Clinician Programmer automatically saves the information. Patient information can include patient demographics, medical notes, physicians, system configuration, programs (including optional stimulation effect scores and amplitude range).

For a patient with a new directSTIM DBS System, manually add the patient to the Clinician Programmer. For patients with a stimulator who are not included in the patient list, import (or pull) patient information from their stimulator to the Clinician Programmer.

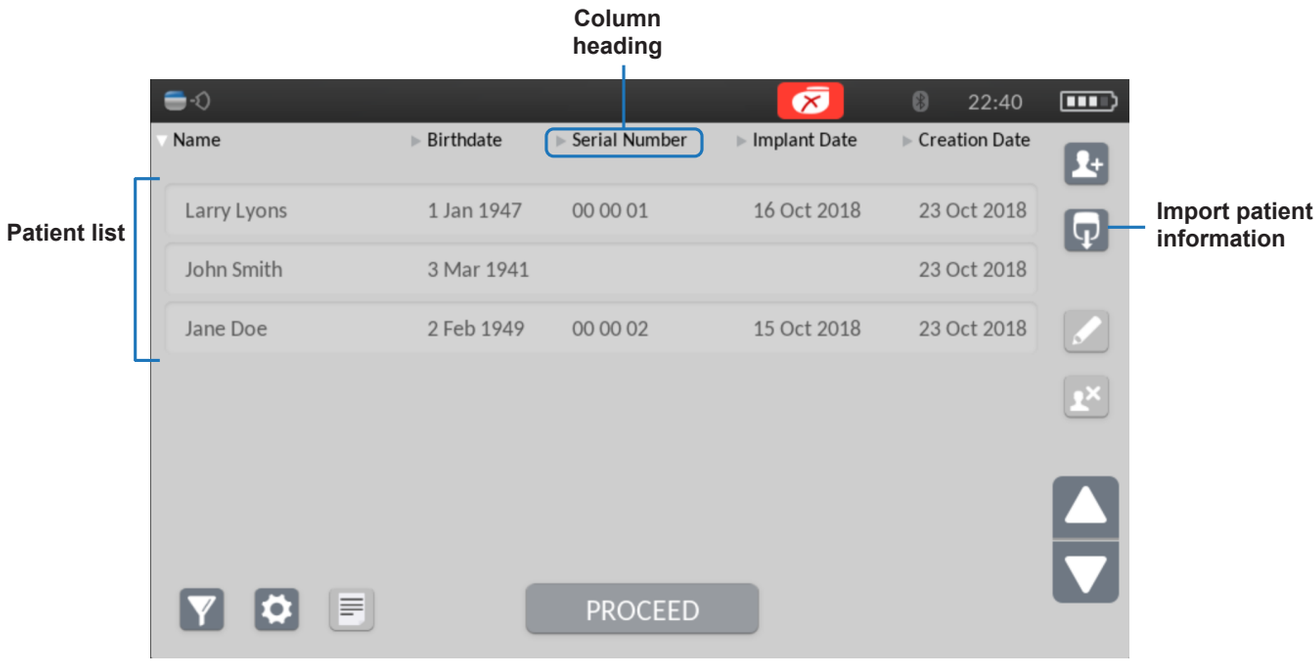
Note: The stimulator has the latest patient information and programs. Importing information from the stimulator provides the latest patient information and programs.

A clinician can access patient information and create or adjust programs for patients included in the patient list. When finished entering or updating patient information, the clinician synchronizes the patient information edited in the clinician programmer with the stimulator, so the stimulator has the latest program adjustments and patient information. Refer to *Manage Programs Task on page 27* for information about synchronizing patient information.

Note: When a clinician selects a patient in the patient list, the Clinician Programmer automatically synchronizes the patient information and programs with the stimulator within range. If needed, the clinician manually imports patient information from a stimulator to the Clinician Programmer to ensure the clinician is working with the latest information. Refer to *Using the Patient List on page 9*.

Using the Patient List

The patient list displays after logging in to the Clinician Programmer. The clinician adds, updates, or deletes patient information, and accesses global Clinician Programmer settings from the patient list.



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Column Headings	Tap to sort displayed information or reverse the sort order.
Patient List	Tap a patient name to select a patient. Drag up or down in the patient list to view additional patients.
	Tap to manually add a new patient to the Clinician Programmer.
	Tap to import (pull) patient information from their stimulator.
	Tap to update patient information.
	Tap to remove a patient.
	Tap to move up and down in the patient list.
PROCEED	Tap to advance to the workflow.
	Tap to view a patient report. Refer to *Reports on page 41* to create a report.
	Tap to access global Clinician Programmer settings, such as display brightness and user accounts. Refer to *Settings on page 33* for more information.
	Tap to filter patients by a physician. Refer to *Physician Administration on page 37* to add a physician.

Adding a Patient

For a patient with a stimulator who is not included in the patient list, the clinician adds the patient using information from their stimulator. For new patients, the clinician manually adds the information to the Clinician Programmer.

To add a patient to the Clinician Programmer from a stimulator:

1. Move the Clinician Programmer within 1 meter of the stimulator.
2. On the patient list, tap to import patient information from a stimulator to ~~a~~ the Clinician Programmer.
3. When the list of nearby stimulators displays:
   a. Tap a stimulator in the list.

      Note: If a stimulator does not display in the list, make sure it is on, nearby, and not connected to another Clinician Programmer or Patient Programmer Charger by turning the programmers off or moving them out of range.

   b. Tap **Confirm**. The patient now displays in the patient list.
4. Tap the patient name, and then PROCEED to advance to the workflow.

To manually add a patient:

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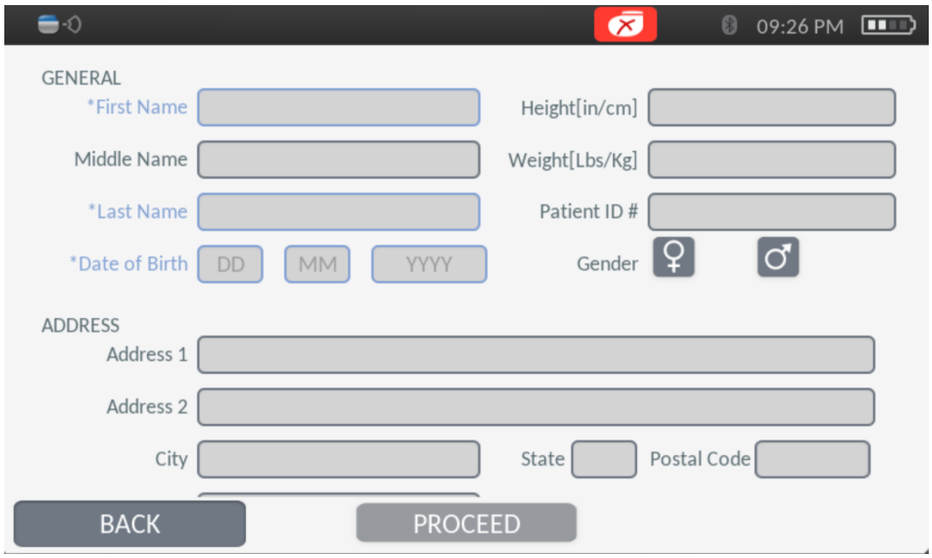
1. From the patient list screen, tap .
2. Enter patient demographics. The required fields are the First Name, Last Name, and Date of Birth.



3. Optionally, tap the Physician Name field to associate a physician with a patient. Refer to *Physician Administration on page 37* to add a physician.
4. Tap PROCEED to advance to the next screen.

   –or–

   Tap BACK to discard changes and return to the patient list.

Updating Patient Information

To update patient information:

1. Tap a patient name in the patient list.
2. Tap .
3. Drag up or down to move to the field you want to update.
4. Tap PROCEED to advance to the workflow.

   Note: Changes are automatically saved to the Clinician Programmer. To manually synchronize patient information, refer to *Manage Programs Task on page 27*.

   –or–

   Tap BACK to discard changes and return to the patient list.

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4. Implants Task

In the Implants task, the clinician adds a stimulator and sets the implant date, adds the leads (one lead for unilateral stimulation or two leads for bilateral stimulation), and configures the connections between them. After completing the Implants task, the clinician advances to the Therapy task to add and adjust programs. As needed, the clinician returns to the Implants task to update the patient's system configuration, such as switching from a trial stimulator to an implantable stimulator or replacing an implantable stimulator.

Adding the Components

To add the components of the patient's system:

1. Tap + to add a stimulator.

2. Select the stimulator from the displayed list of stimulators within range (1 meter).

   The implantable stimulator packaging material and the front of the stimulator include the serial number. The trial simulator serial number is on the label on the back of the stimulator.

   Note: If the stimulator is not displayed on the list, verify the stimulator is on, nearby, and not connected to another Clinician Programmer or Patient Programmer Charger by turning the programmers off or moving them out of range.

   If needed, tap **Search** to refresh the list of stimulators.

3. Tap **Accept**.

   on the status bar indicates the Clinician Programmer is communicating with the stimulator.

4. Use the arrows to adjust the implant date, if needed, and then tap SAVE on the implant date dialog.

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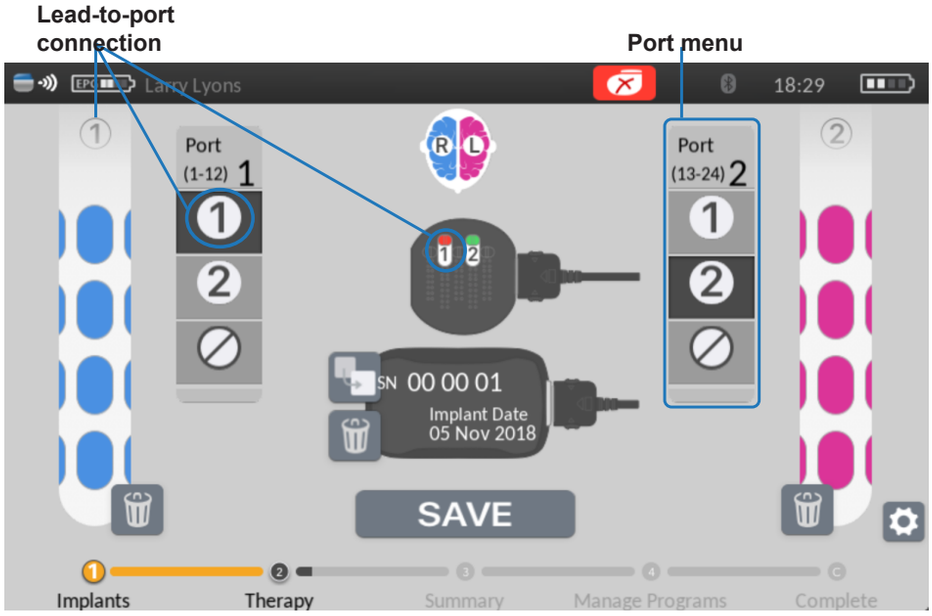
5. Tap **Accept** to save the implant date to the stimulator. An image of the selected stimulator displays.
6. Tap + to add a lead.

Continue to *Configuring the Lead-to-Port Connections on page 14.*

Configuring the Lead-to-Port Connections

After adding the system components, the clinician specifies the lead connected to each port of the stimulator.



1 2	Tap in the Port menu to indicate the port on the stimulator to which a lead is connected.
1 2	The selected port displays on the lead.
⊘	Tap to indicate a lead is not connected to a port.

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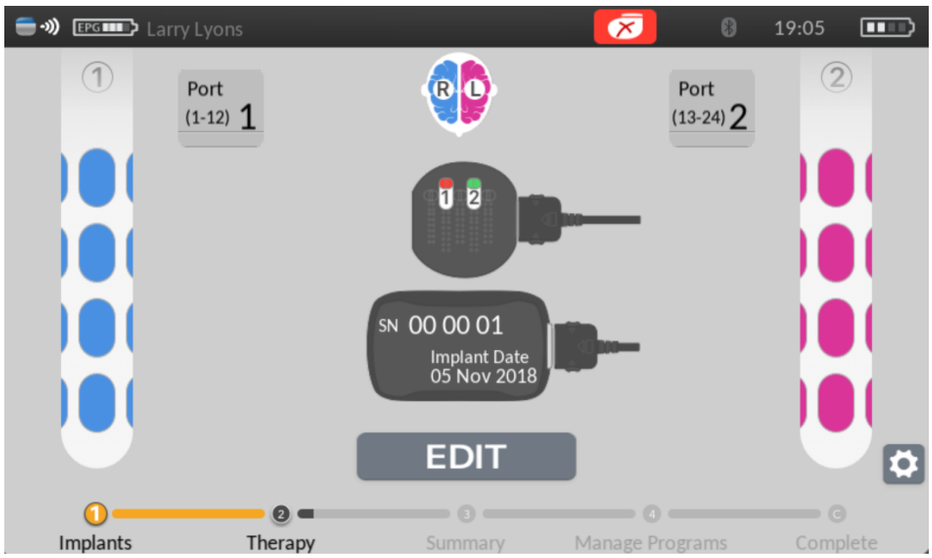
SAVE	Tap to save the system configuration. Continue to the *Therapy Task on page 17*.
	View the color-coded hemisphere while configuring directSTIM DBS System components.
	Tap to replace the stimulator. Refer to *Replacing a Stimulator on page 15*.
	Tap to delete leads or the stimulator from the configuration. For more information, refer to *Removing Components on page 16*. **Note:** Delete leads first, and then delete the stimulator. Deleting a lead deletes all associated programs.
SN	Displays the serial number of the stimulator.
Implant Date	Displays the implant date of the stimualtor.
	Tap to adjust Clinician Programmer or stimulator-related settings. Refer to *Settings on page 33* for more information.

Replacing a Stimulator

Replace a trial stimulator with an implantable stimulator, a trial stimulator with another trial stimulator, or an implantable stimulator with another implantable stimulator.



Note: When replacing a stimulator, all patient information and programs are automatically transferred from the existing stimulator to the new stimulator, and all scores are cleared from the Effect Boards. Refer to *Scoring Beneficial Effects and Side Effects (Optional) on page 22* for more information about Effect Boards.

To replace a stimulator:

1. Tap the **Implants** task in the workflow.
2. Tap EDIT.

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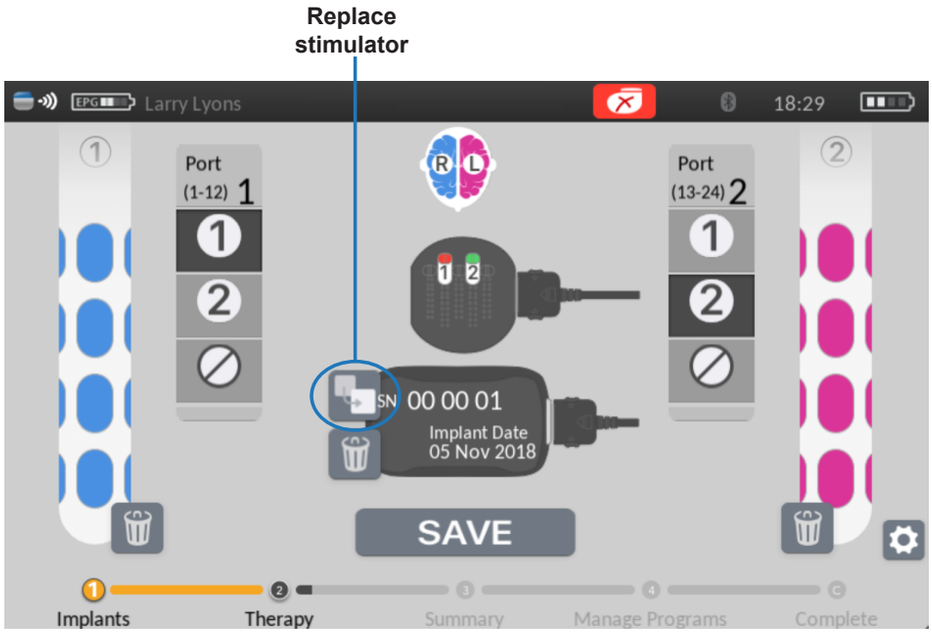
3. Tap next to the stimulator.



4. Tap **Search** on the displayed dialog to find stimulators within range.
5. Tap a stimulator in the displayed list.

   The implantable stimulator packaging material and the front of the stimulator includes the serial number. The trial simulator serial number is on the label on the back of the stimulator.

   Note: If the stimulator is not displayed on the list, verify the stimulator is on, nearby, and not connected to another Clinician Programmer or Patient Programmer Charger by turning the programmers off or moving them out of range.

   Tap **Search** to refresh the list.
6. Tap **Accept** to confirm the change.

   A status message indicating the successful transfer of information to the new stimulator displays.
7. Tap **Close** on the popup message. An image of the selected stimulator displays on the Implants screen.

   Note: The lead-to-port configuration and configured programs from the original stimulator remain the same for the replacement stimulator. The current date replaces the originally configured implant date.
8. Tap SAVE.

Removing Components

Remove the leads before removing the stimulator.

To remove configured components:

1. Tap EDIT.
2. Tap to remove a lead or a stimulator.
3. Tap **Accept** to confirm deleting a lead.

Return to *Adding the Components on page 13* to reconfigure components.

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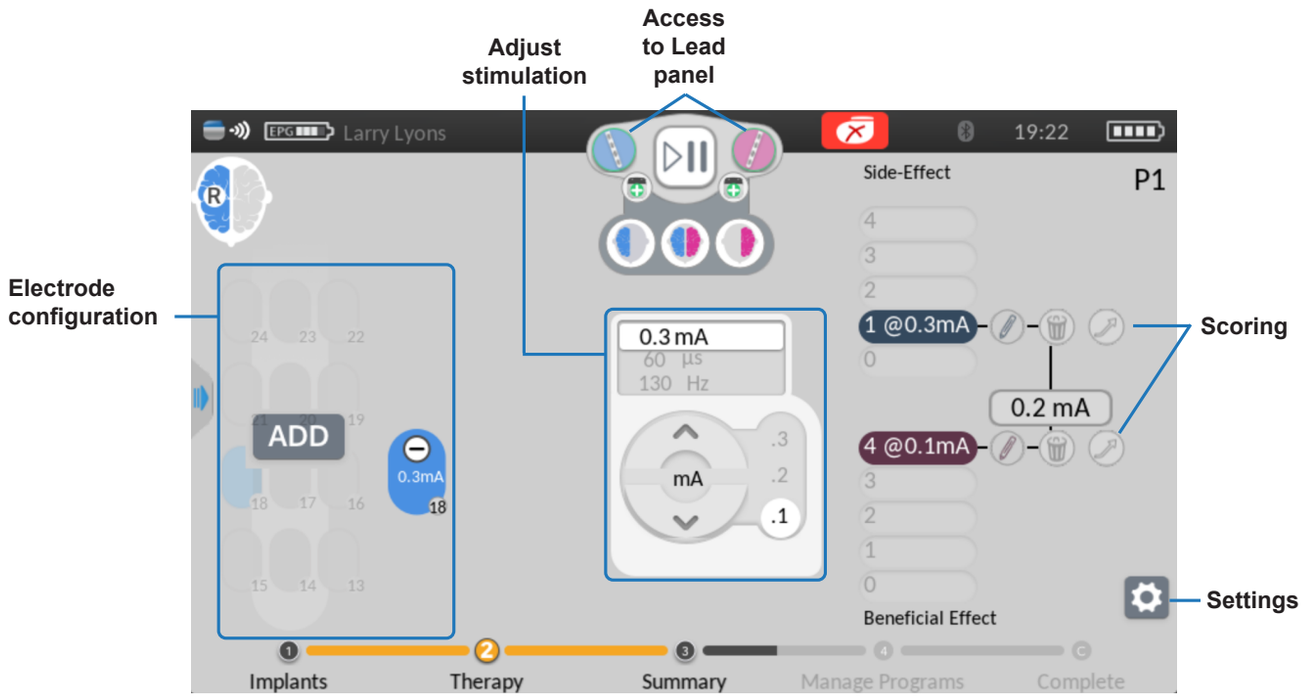
5. Therapy Task

After configuring the system components in the Implants task, the clinician advances to the Therapy task to configure, test, score, and adjust stimulation before continuing to the Summary task. The clinician saves the configured stimulation as a program in the Summary task. A program is a combination of an electrode configuration and stimulation parameters (amplitude, pulse width, and frequency) used to deliver unilateral or bilateral stimulation to meet the patient's stimulation needs.



Using the Therapy Task Screen

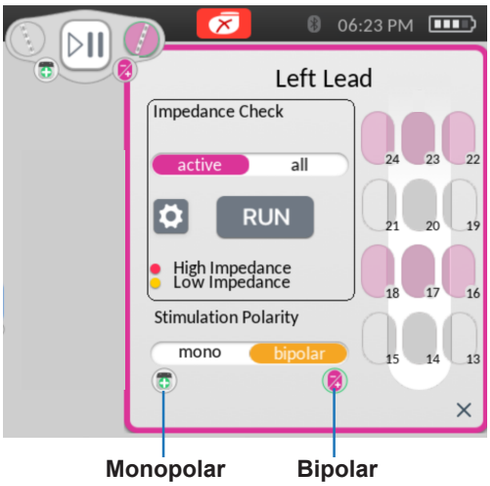
Use the functions available in the Therapy task to configure stimulation, test stimulation configurations, score the side effects and beneficial effects of stimulation, and save the stimulation configuration for comparison.

Hemispheres

Tap to switch between configuring settings for the right (blue) and left (pink) hemispheres.

Note: With unilateral stimulation, you can program only one hemisphere.

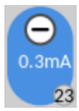
Stimulation Polarity

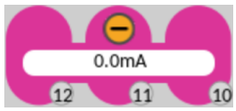


On a Lead panel, slide to **Mono** (default) or **Bipolar** to set stimulation polarity.

- The selected electrodes are cathodes (-) and the can is the anode.
- One row (3 electrodes) is the cathode and one to three selected rows are anodes (+). The clinician can change the polarity of a row.

Electrode Configuration

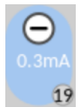


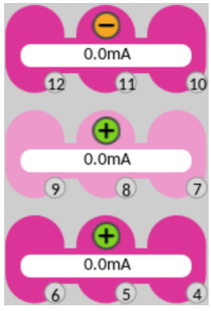


Tap to configure an electrode or row of electrodes. Configure amplitude and pulse width for one or more electrodes. The hemisphere color, electrode polarity, amplitude value, and electrode number are displayed on the configured electrodes.

The Clinician Programmer automatically balances the amplitude for configured electrodes to ensure the total amplitude distribution is always 100%.

Note: The maximum amplitude for an electrode is 6.4 mA.





Tap to lock an electrode or row of electrodes. Locked electrodes stay at the current amplitude and turn to a lighter shade of blue or pink.

Note: You can only lock a row of bipolar electrodes after selecting a cathode row and two or three anode rows.

The Clinician Programmer does not change the amplitude of a locked electrode. Tap the electrode or row of electrodes again to unlock it.

Electrode that is not programmed.

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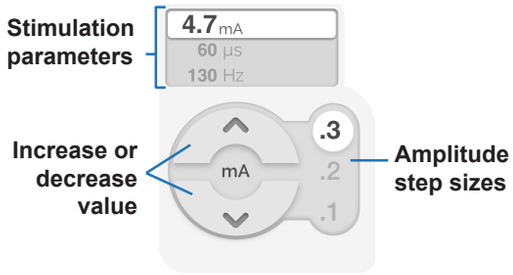
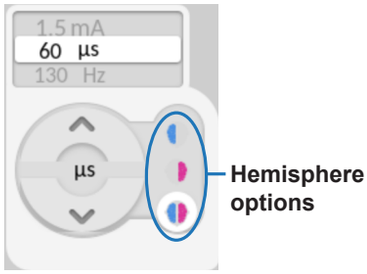
Stimulation Settings



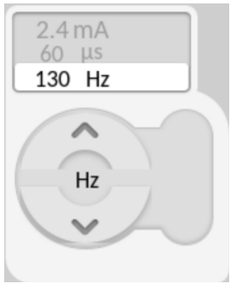
Tap amplitude and then a step size to increase amplitude by the selected amount.

Tap the arrows to increase or decrease amplitude.



Tap pulse width and the right, left, or both hemisphere option to adjust the pulse width for one or both leads.

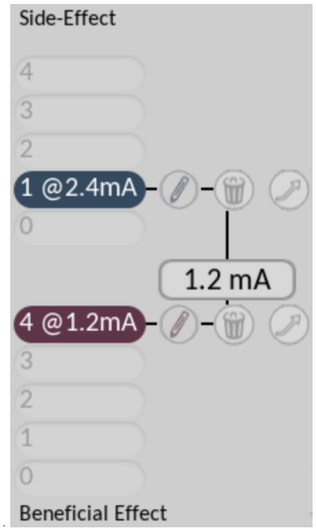
Tap the arrows to increase or decrease pulse width.



Tap frequency to adjust the frequency for the program.

Tap the arrows to increase or decrease frequency.

Scoring



Tap 0-4 to score the effects of stimulation for different combinations of configured electrodes and stimulation parameter values. Refer to *Scoring Beneficial Effects and Side Effects (Optional) on page 22.*

Settings

Tap to access global Clinician Programmer and stimulator settings. Refer to *Settings on page 33.*

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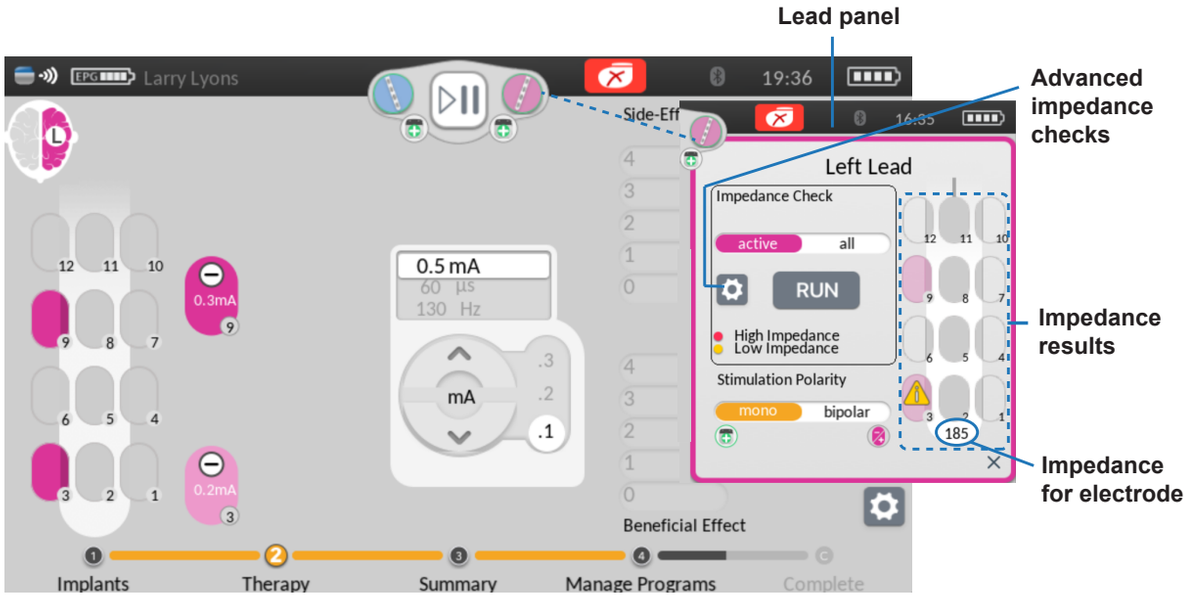
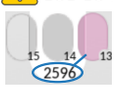
Performing an Impedance Check (Optional)

While implanting the system leads and extensions, a physician can use a trial stimulator to verify lead and extension integrity by performing an impedance check. After the extensions are connected to an implanted stimulator, the physician can perform an impedance check to verify the integrity of the system.

Note: If the trial stimulator stops for an unknown reason, replace the trial stimulator with a new one.

For information about advanced impedance checks, refer to *Advanced Impedance Checks on page 38*.



	Tap to access the lead panel to perform impedance checks.
	Slide to **Active** (default) to measure impedance between configured electrodes and the can or the ground pad (conntected to a trial stimulator) or **All** to measures impedance between all electrodes and the can or the ground pad.
	Tap to initiate an impedance check. Results display on the lead. Tap an individual electrode to display the impedance of the electrode. **Results:** • No indication when within range (250 - 9,000 Ohms) • for high impedance (> 9,000 Ohms) • for low impedance (< 250 Ohms) •  Displays impedance for the selected electrode
	Tap to access impedance checks. Refer to *Advanced Impedance Checks on page 38* for instructions.

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Configuring Stimulation

The clinician configures electrodes and stimulation parameters, optionally scores the beneficial and side effects of stimulation, and saves the configuration and scores to the Effect Board for comparison.

To configure stimulation:

1. Access the lead panel to change stimulation polarity, if needed. Refer to *Stimulation Polarity on page 18*.
2. Tap to select the electrodes or rows of electrodes that will deliver stimulation. In case of bipolar stimulation, tap at least two electrode rows.
3. Optionally, for bipolar stimulation tap ⊕ or ⊖ to change the polarity.
4. Set the amplitude for the selected electrodes.

   Note: Changes to amplitude are not applied to locked electrodes. Refer to *Electrode Configuration on page 18*.
5. Optionally, adjust the pulse width for one or both leads or adjust the frequency for the program. Refer to *Stimulation Settings on page 19* for more information.

   Notes:

   » Amplitude, pulse width, and frequency parameters are related. The Clinician Programmer displays a message when the maximum value for a parameter is reached.

   » The program frequency limit is 150 Hz when stimulation polarity is set to bipolar for a lead.
6. Optionally, score the beneficial effect and side effect of stimulation and tap ADD to save the configuration and scores to the Effect Board. Refer to *Scoring Beneficial Effects and Side Effects (Optional) on page 22* for instructions.

Delivering Test Stimulation (Optional)

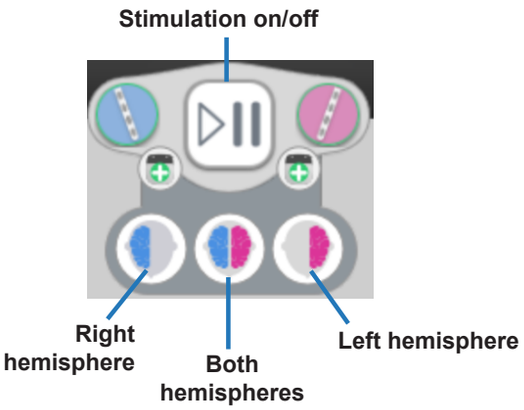
The clinician can use the Clinician Programmer and a trial stimulator to deliver test stimulation during intraoperative testing. Once the system components are implanted, the clinician can deliver test stimulation while programming and optionally score stimulation. When the configured stimulation produces desirable results for the patient, the clinician saves the configuration as a program.

Note: If the Clinician Programmer loses communication with the stimulator during test stimulation, stimulation automatically stops.

To turn stimulation on and off:

1. Tap ⏯ and then the right, both, or left hemisphere to start stimulation. Stimulation ramps to the set amplitude.

   The stimulation on/off button turns green. The stimulation and lead buttons flash while stimulation is on.



2. Optionally, adjust stimulation settings while stimulating and record beneficial effect and side-effect scores.

   Caution: Increase amplitude slowly. Increasing amplitude quickly may cause undesirable stimulation effects.
3. Tap ⏯ and then a hemisphere option. Stimulation ramps to zero and the buttons stop flashing.

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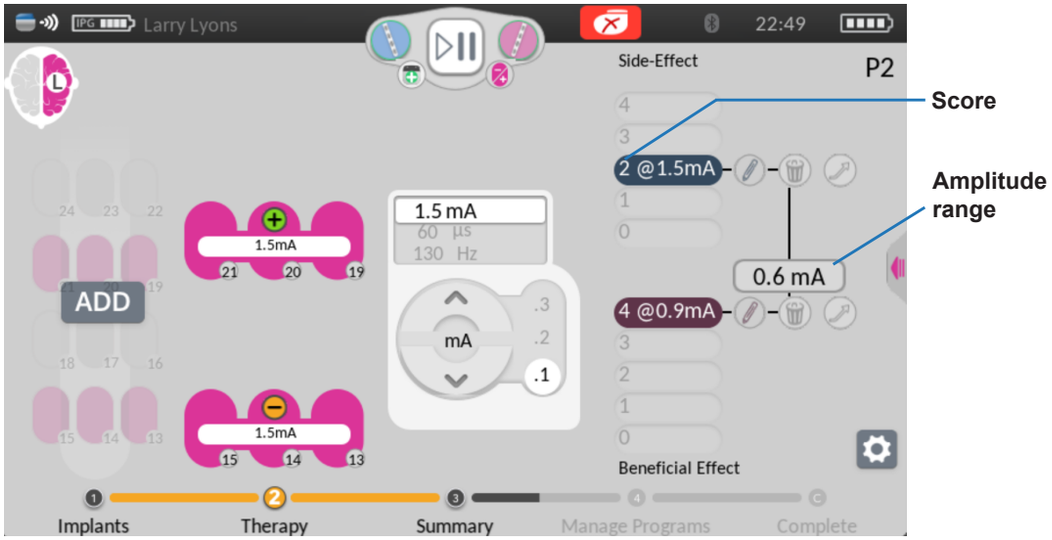
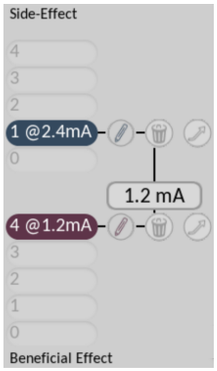
Scoring Beneficial Effects and Side Effects (Optional)

The clinician scores the effects of stimulation for different electrode and amplitude configurations and adds the configuration and scores to the collection of therapeutic windows on the Effect Board. A therapeutic window is the range of amplitude in which the patient experiences a beneficial effect and a side effect to stimulation. The clinician uses the Effect Board to view and select the therapeutic window that provides the greatest benefit to the patient.





Tap 0–4 to score the effects of stimulation; 0 indicates no effect and 4 indicates the greatest beneficial effect or side effect of stimulation. The amplitude set for each effect displays with the score.

Tap a beneficial effect score when stimulation beneficially changes the patient's symptoms. Adjust amplitude until the patient experiences a side effect and then score the side effect.

After selecting a beneficial effect and side-effect score, the amplitude range between scores displays. The amplitude range between scores is the therapeutic window.

Tap to select a stimulation-related effect. A list of predefined effects display.

Tap **Custom** to enter an unlisted effect.

Tap to delete a score.

Note: The electrode configuration and stimulation setting are not deleted.

Tap to stimulate at the scored amplitude.

Tap to save the stimulation configuration and scores to the collection of therapeutic windows on the Effect Board. Once saved, the Clinician Programmer clears the most recent configuration so the clinician can configure a new therapeutic window.

Note: Replacing a stimulator or lead clears all scores from the Effect Boards.

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To score the effects of stimulation as a therapeutic window:

1. Adjust stimulation parameters.
2. Start stimulation. Refer to *Delivering Test Stimulation (Optional) on page 21*.
3. When a benefit occurs, tap the bottom 0–4 slots to score the beneficial effect. The selected beneficial effect slot turns burgundy, and displays the score and the current amplitude. You can continue to increase or decrease the amplitude and change the beneficial effect score.
4. Tap next to the score to select a specific beneficial effect or manually enter a custom effect.
5. Adjust amplitude until a patient exhibits a side effect.
6. When a side effect occurs, tap the top 0–4 slots to score the side effect. The selected side-effect slot turns blue, and displays the score and the current amplitude.
7. Tap to select a specific side effect or manually enter a custom effect. The amplitude range between the beneficial effect and the side effect displays.
8. Tap ADD. The Clinician Programmer saves the configuration and the beneficial and side-effect scores as a new therapeutic window on the Effect Board.

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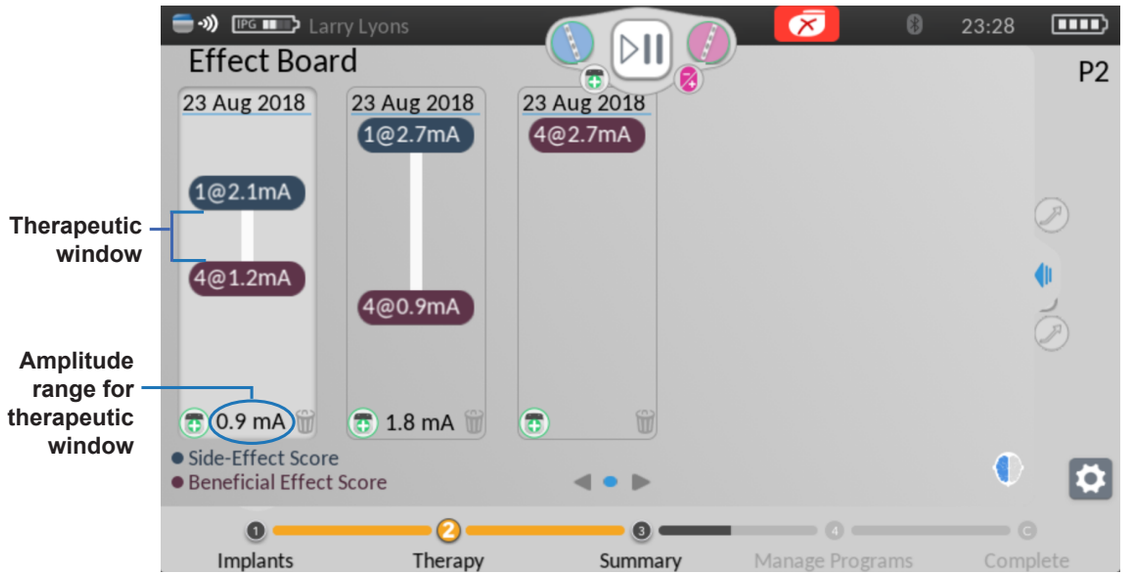
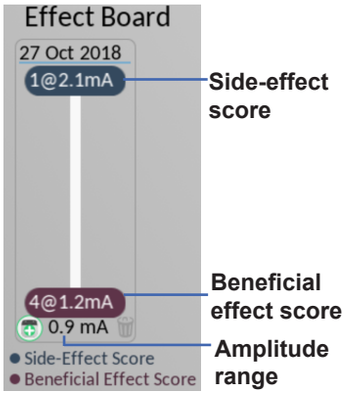
Selecting a Therapeutic Window (Optional)

The collection of therapeutic windows display on the Effect Board. An Effect Board is available for each configured lead. Use the Effect Board to compare the therapeutic windows.



	Tap to open and close the Effect Board.
	Open an Effect Board to view the saved therapeutic windows, which display the scores and amplitude. The bottom of the window displays the amplitude range for the therapeutic window. The amplitude range is the difference between the amplitudes associated with the beneficial effect score and the side-effect score. Tap a therapeutic window and close the board to display the corresponding stimulation configuration and scores on the Therapy task. After adjusting the configuration or scores, tap ADD to save the changes as a new therapeutic window on the Effect Board. **Note:** If stimulation is on when you access an Effect Board, the Clinician Programmer automatically turns stimulation off if you select a different therapeutic window and close the Effect Board.
	Shows the stimulation polarity of the lead.
	Tap to view the previous or next five therapy windows.

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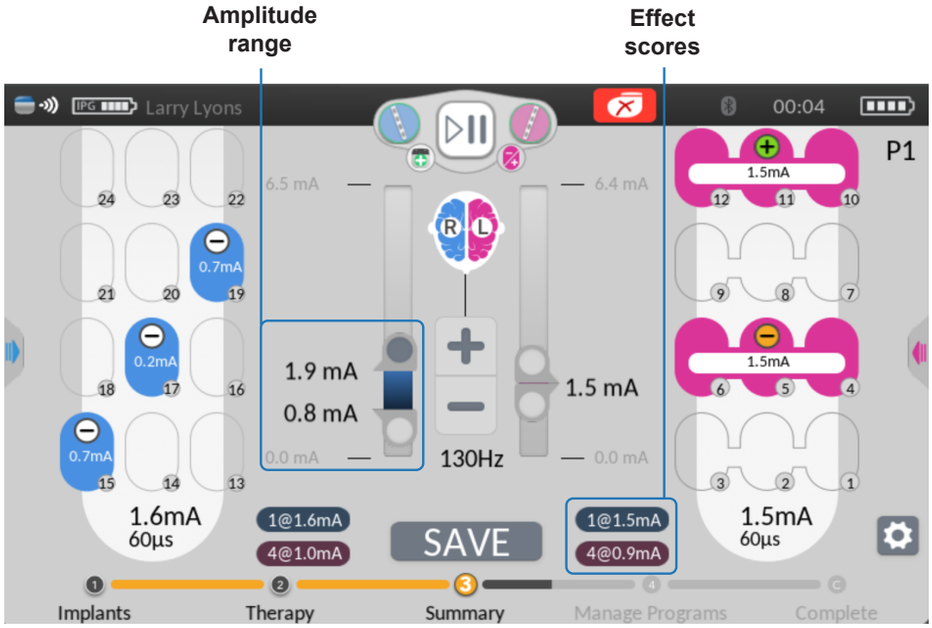
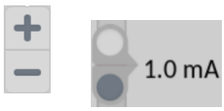
6. Summary Task

Advance to the Summary task after configuring stimulation for a patient in the Therapy task. The settings that display in the Summary task make up a program. Optionally, on the Summary screen the clinician can set an amplitude range for a program to give a patient the ability to adjust stimulation with their Patient Programmer Charger. For each patient, the clinician can create up to four programs. After saving the configuration as a program, the Clinician Programmer automatically advances to the Manage Programs task.



	Tap and then select the right, both, or left hemisphere to start stimulation. Stimulation ramps to the set amplitude. The stimulation on/off button turns green. The stimulation and lead buttons flash intermittently while stimulation is on. **Note:** Stimulation remains on when moving from the Therapy task to the Summary task.
	Tap or slide to set a range in which a patient can adjust amplitude for a program with their Patient Programmer Charger. **Caution:** Using the Pulse amplitude adjustment only on one side may not display on the PPC. Apply Pulse amplitude Adjustement on both sides with a minimum range of 0.4mA per side. **Note:** If you do not want a patient to have the ability to adjust amplitude, make sure the sliders do not display an amplitude range.
	Tap to view or select a therapeutic window from the Effect Board. Refer to *Selecting a Therapeutic Window (Optional) on page 24*.
	Tap to adjust the Clinician Programmer and stimulator settings. Refer to *Settings on page 33*.

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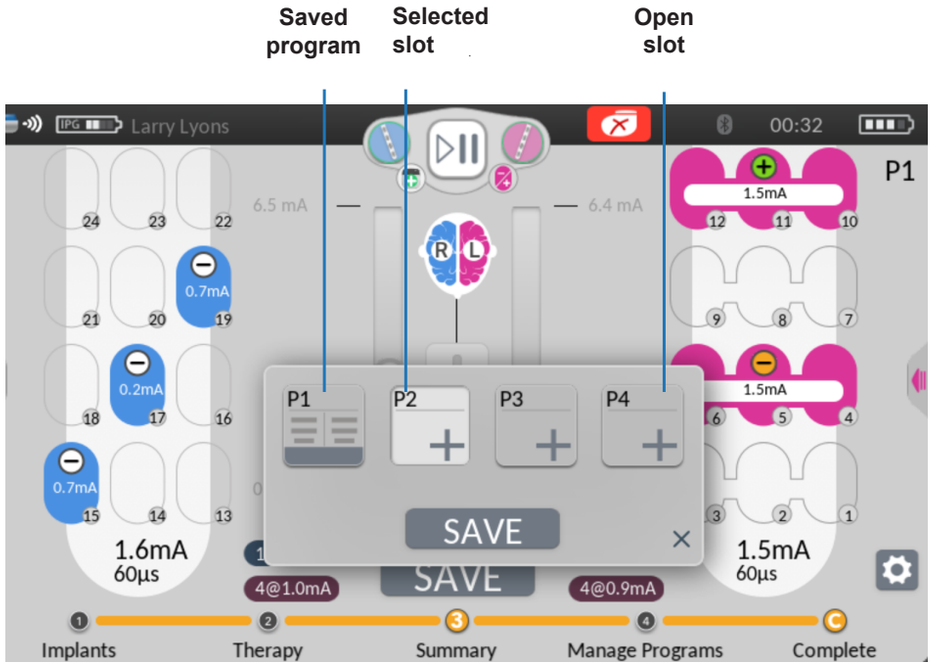
Saving a Program

To save a program:

1. Tap SAVE.
2. Select a free slot amongst P1 - P4.



3. Tap SAVE on the program popup.

   The Clinician Programmer automatically advances to the Manage Programs task where the clinician can synchronize patient information and programs with the patient's stimulator. Refer to *Manage Programs Task on page 27*.

4. If you selected a slot already containing a program the action proposed is to REPLACE.

   Caution: Do not use the REPLACE button if the modified program had pre-existing scoring data. If you used the REPLACE button in such situation, you will see a pop-up message indicating that the program cannot be push to the IPG. In such event, please refer to instructions in *troubleshooting section page 48*.

   Note: The Clinician Programmer stops stimulation when you save a program and advance to the Manage Programs task.

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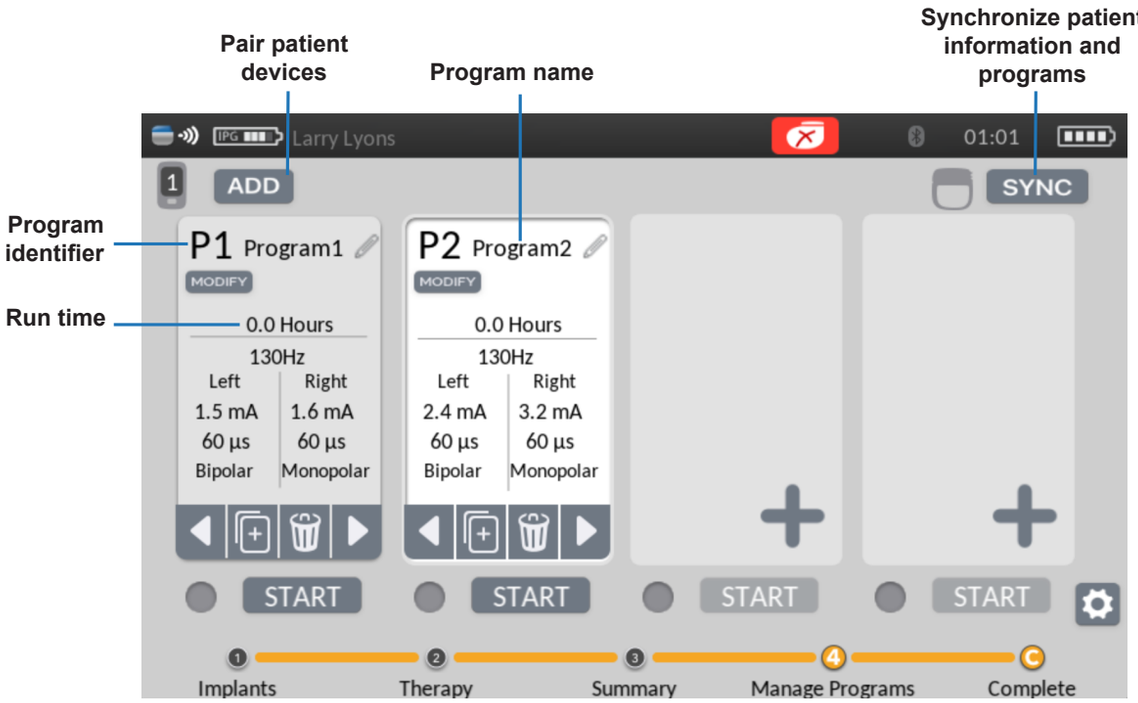
7. Manage Programs Task

After saving or replacing a program in the Summary task, the Clinician Programmer automatically advances to the Manage Programs task. On the Manage Programs task, the clinician manages, reorders, deletes, or adjusts existing programs for a patient. New or updated programs are available to the patient after the clinician synchronizes patient information and programs with the stimulator and has paired at least one Patient Programmer Charger with the stimulator.

After synchronizing patient information and programs with the stimulator, the clinician can start stimulation from the Manage Programs task or the patient can use their paired Patient Programmer Charger to start a program.



ADD	Tap to pair Patient Programmer Chargers with the stimulator. The clinician can pair up to three Patient Programmer Chargers. The serial number for a Patient Programmer Charger is located on the label on the back of the programmer. Refer to *Patient Programmer Charger Pairing on page 40* for instructions.
2	Displays the number of paired devices.
	Displays when there is a mismatch between patient information and programs on the Clinician Programmer and the stimulator.
SYNC	Tap SYNC and then tap **Push** on the displayed message popup to synchronize patient information and programs with the stimulator. After synchronizing patient information and programs, the programs are available to the patient on a Patient Programmer Charger.
Program1	Tap to enter a custom program name. Patients see the program name on their Patient Programmer Chargers.
MODIFY	Tap to return to the Therapy task and modify a program. Refer to *Configuring Stimulation on page 21*.
0.0 Hours	View the amount of time a program has run. **Note:** When a clinician modifies a program, run time for the program resets.

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	Tap **Start** after synchronizing patient information and programs with the stimulator to start stimulation. The indicator turns green and **Start** changes to **Stop** while stimulation is on. Stimulation continues until stopped.
	Tap to move a program to a different slot. **Note:** Programs display on the Patient Programmer Chargers in the order in which they display on the Manage Programs task.
	Tap to copy a program.
	Tap to delete a program.
	Tap to add a program. The Clinician Programmer returns to the Therapy task so the clinician can configure stimulation parameters. Refer to *Configuring Stimulation on page 21*.

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8. Using a Trial Stimulator (Optional)

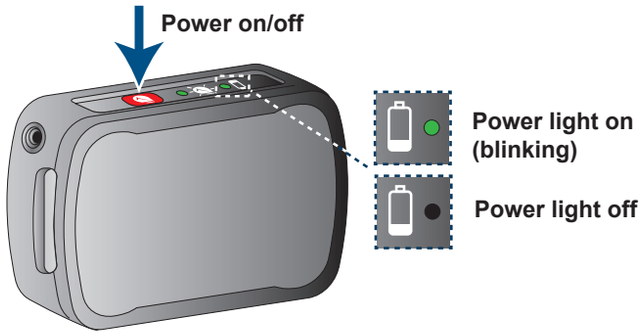
During a DirectSTIM DBS System implant or replacement of leads or extensions, a physician may use a trial stimulator to perform intraoperative testing to verify lead and extension functionality. Use the instructions in this section to connect a trial stimulator and then refer to *Performing an Impedance Check (Optional) on page 20* and *Delivering Test Stimulation (Optional) on page 21* to performing testing with the Clinician Programmer and the trial stimulator.

Checking the Battery Level and Stimulation

Note: Use to power on the trial stimulator or turn stimulation off.

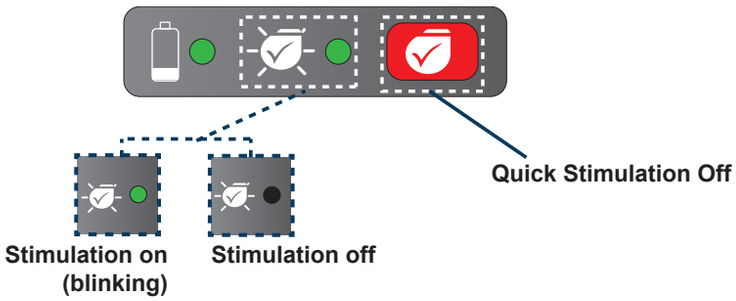
1. Turn the trial stimulator on by pressing and holding for approximately **five seconds.** After a short delay, the trial stimulator power light blinks green to indicate the trial stimulator is on.

   Note: If the trial stimulator power light flashes red, replace the trial stimulator batteries. Refer to *Changing the Batteries on page 30* for instructions.



2. When the trial stimulator is on, verify that stimulation is off by looking at the stimulation on/off light. If the stimulation light is blinking green, press and hold for approximately **two seconds**. After a short delay, stimulation turns off, and the stimulation on/off light turns off.

   Note: Stimulation is delivered to the patient only when the leads or extensions are connected to the trial cable, and the trial cable and ground pad are connected to the trial stimulator.



3. Turn the trial stimulator off by pressing and holding for approximately **five seconds.**

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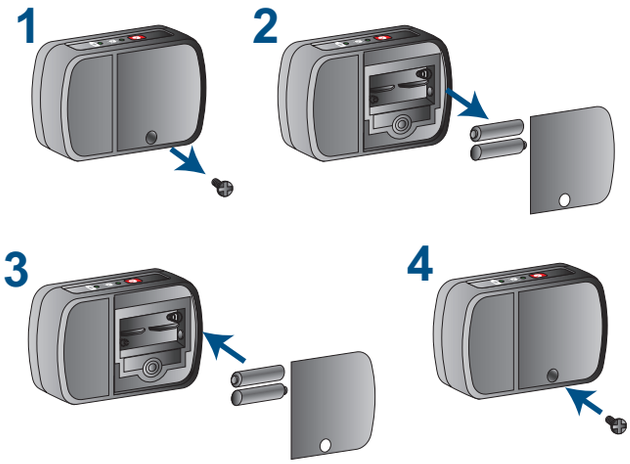
Changing the Batteries

Caution: Do not leave depleted batteries in the trial stimulator. The batteries may corrode and cause damage to the electronic components. If the trial stimulator will be idle for several weeks, remove the batteries.



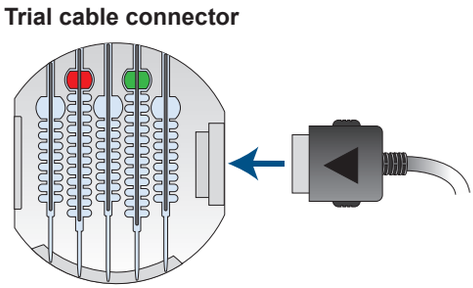
To change the batteries in the trial stimulator:

1. Using a Phillips screwdriver, loosen the screw on the battery compartment cover.
2. Remove the battery compartment cover and batteries.
3. Insert two new AAA batteries following the polarity diagram in the battery compartment.
4. Replace the battery compartment cover, then insert and tighten the screw.

Connecting the Trial Cable

Caution: The trial cable is a single-use component. Do not resterilize the trial cable because of risk of infection.

1. With the arrow on the cable plug facing up, connect the trial cable to the trial cable connector.



2. Hold the proximal end of the lead or extension. With a lead, partially remove the stylet so the stylet handle does not prevent the lead from sliding into the lead groove.

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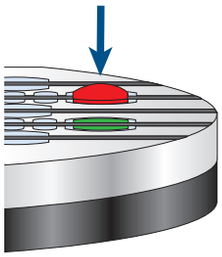
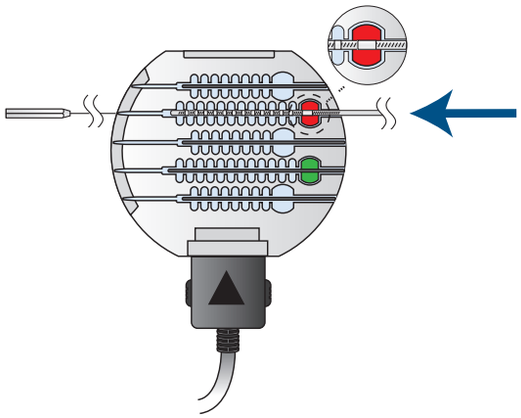
3. Verify that the lead locks in the trial cable connector are open.
   a. Hold the connector level. The lead locks should fall into the down (open) position.
   b. If the lead lock is up (closed position), push the lead lock down.

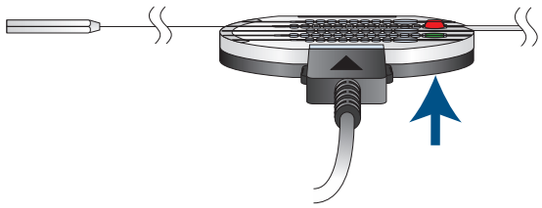


4. Fully slide the proximal end of the lead or extension into a groove with a red or green lock. The lead lock colors correspond to the Clinician Programmer software and trial stimulator connector ports: port 1 (red) and port 2 (green).

   Note: If resistance is felt when sliding the proximal end of the lead or extension into the groove, verify the lead lock is fully open (down).



5. Push up on the lead lock to secure the proximal end of the lead or extension in place.



6. To prevent the proximal end of the lead or extension from moving, secure the trial cable to the drape before passing the end of the cable off the sterile field.
7. Pass the end of the cable out of the sterile field, and then secure the cable to the drape outside the sterile field.

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Connecting the Trial Stimulator

1. Verify stimulation is off on the trial stimulator. Refer to *Checking the Battery Level and Stimulation on page 29*.

   Caution: Make sure that stimulation is off before connecting the trial cable to the trial stimulator. Connecting the trial cable to the trial stimulator with stimulation on may cause uncomfortable stimulation.

2. Affix a ground pad to the patient in an approximate location, such as the flank, back, or heel.

   Note: The ground pad is non-sterile.

   a. Verify there is no wounded skin in the application area, and then clean and dry the application area.

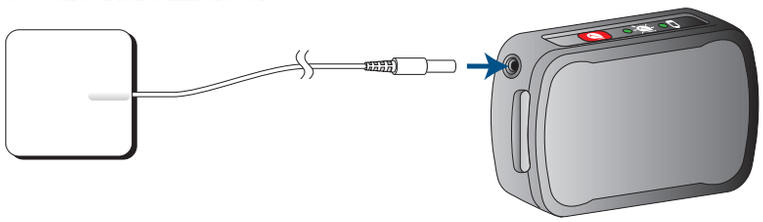
   b. Lift the edge of the ground pad, and then peel it from the release sheet.

      Note: Do not pull on the ground pad wire.

   c. Affix the ground pad to the application area, holding the pad in place for 15 seconds.

   Note: If the ground pad gel is dry, verify that the ground pad is disconnected from the trial stimulator. Rub a few drops of water over the gel, then wait a few minutes before affixing the ground pad to the application area.

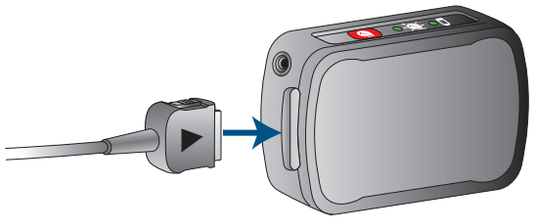
3. Connect the ground pad to the trial stimulator.



4. With the arrow on the cable end facing the front of the trial stimulator, connect the trial cable to the trial stimulator.

   Caution: Maintain adequate slack in the cable. Pulling the cable taut may dislodge an implanted lead.

   Note: If the trial cable fails when connecting a lead or extension, replace the trial cable with a new one.



5. Turn the trial stimulator on by pressing and holding for approximately **5 seconds**. Use the Clinician Programmer to configure the directSTIM DBS System components and perform intraoperative testing. Refer to *Implants Task on page 13* to configure components and *Therapy Task on page 17* to perform impedance checks and deliver test stimulation.

   Note: If an impedance check indicates an open circuit, replace the trial cable with a new one.

Removing the Trial Stimulator

After conducting intraoperative testing, disconnect the leads or extensions from the trial stimulator.

1. On the Clinician Programmer, tap on the Therapy or Summary task to turn off stimulation.
2. Turn off the trial stimulator. Refer to *Checking the Battery Level and Stimulation on page 29* for instructions.

   Note if the extensions are inserted into the top (red lead lock) or bottom (green lead lock) groove in the trial cable connector. The extension will be inserted into the stimulator port matching the trial cable connector groove position.
3. Gently disconnect the leads or extensions from the trial cable connector.
4. Disconnect the ground pad from the stimulator.

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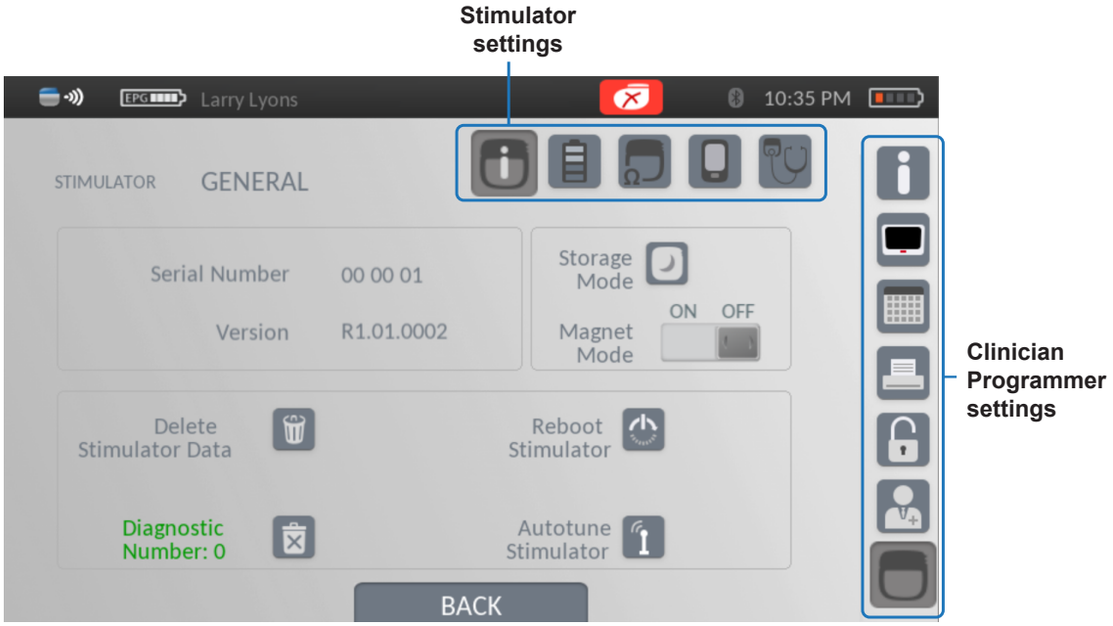
9. Settings

The clinician can view information about the Clincian Programmer and stimulator, or adjust general settings by tapping ⚙ on any screen.

Note: Tapping ⚙ on the patient list displays only the Clinician Programmer settings.



Clinician Programmer Settings		Tap to view information about the Clinician Programmer, including version, model, and serial numbers.
		Tap to change display settings for the Clinician Programmer. Refer to *Display on page 35*.
		Tap to set the time and date for the Clinician Programmer. Refer to *Time & Date on page 36*.
		Tap to print a test page to test the connection to a printer. Refer to *Printer Management on page 36*.
		Tap to add user accounts for the Clinician Programmer and change user passwords. Refer to *User Administration on page 37*.
		Tap to add physicians, which enables filtering patients by physician on the patient list. Refer to *Physician Administration on page 37*.

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Stimulator Settings		Tap to display stimulator settings. **Note:** The Stimulator settings are available after the clinician adds a stimulator for a patient in the Implants task. Tap ⚙ on a workflow task to access stimulator settings.
		View information about the stimulator and configure stimulator settings.
		View battery statistics and Elective Replacement Interval (ERI) information. Refer to *Battery & ERI on page 38*.
		Perform advanced impedance checks. Refer to *Advanced Impedance Checks on page 38*.
		Pair Patient Programmer Chargers to a stimulator. Refer to *Patient Programmer Charger Pairing on page 40*.
		Tap when instructed to do so by Aleva Customer Service.
	Serial Number	The serial number of the stimulator.
	Version	The software version on the stimulator.
		Tap to place the stimulator in storage mode. To take the stimulator out of storage mode, refer to the Patient System Manual.
	Magnet Mode	Slide to turn magnet mode on or off. When on, the patient can use the directSTIM DBS System Magnet Model 12700 to turn stimulation on or off. Refer to the Patient System Manual for instructions. **Note:** Regardless of this setting, you can always use a magnet to turn stimulation off or place an implantable stimulator into storage mode.
		Tap to remove all patient and program information from the stimulator.
		Tap to reboot the stimulator, which stops stimulation and reinitializes the internal settings. **Note:** This does not affect the patient information or programs on the stimulator.
		Tap to clear the displayed diagnostic number on the stimulator. If there is more than one diagnostic number, repeat to clear additional numbers.
		Tap to notify the stimulator to optimize communication. Autotune the stimulator if you or the patient experience reduced communication between the stimulator and the Patient Programmer Charger or Clinician Programmer. This may happen when the tissue surrounding the stimulator changes, such as after healing from surgery.
		Return to the previous screen.

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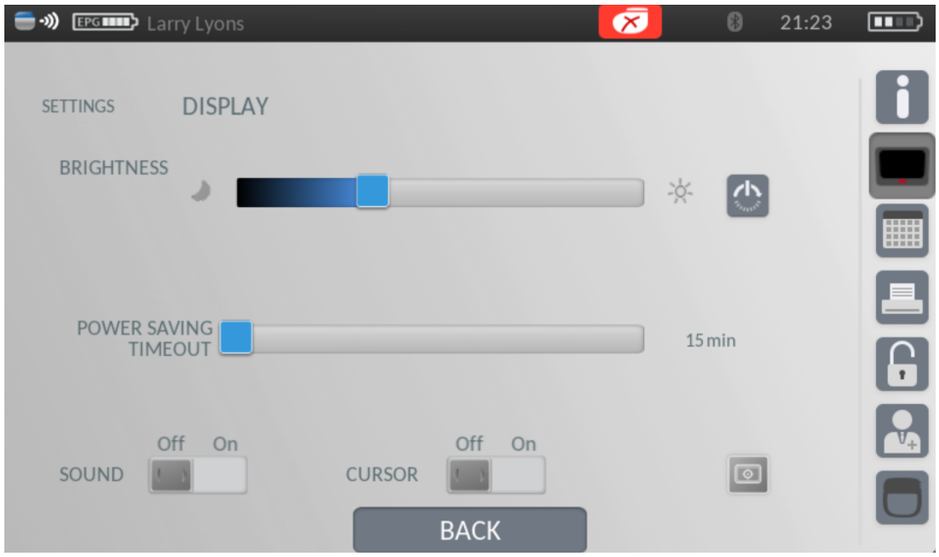
Display



Brightness	Slide to adjust the brightness of the screen. **Note:** The screen brightness affects the rate at which the battery discharges.
Power Saving Timeout	Slide to adjust the time at which the Clinician Programmer shuts down. **Note:** The Clinician Programmer screen dims after two minutes with no use.
Sound	Tap to turn on or off the click sound that occurs when tapping the screen.
Cursor	Tap to turn on or off the cursor indicator that displays when tapping the screen.
	Tap to reset the display settings to the factory defaults.
	Tap to recalibrate the screen. Follow the instructions displayed on the screen. You may need to recalibrate the screen if you touch an image on the screen and the Clinician Programmer does not react as expected.

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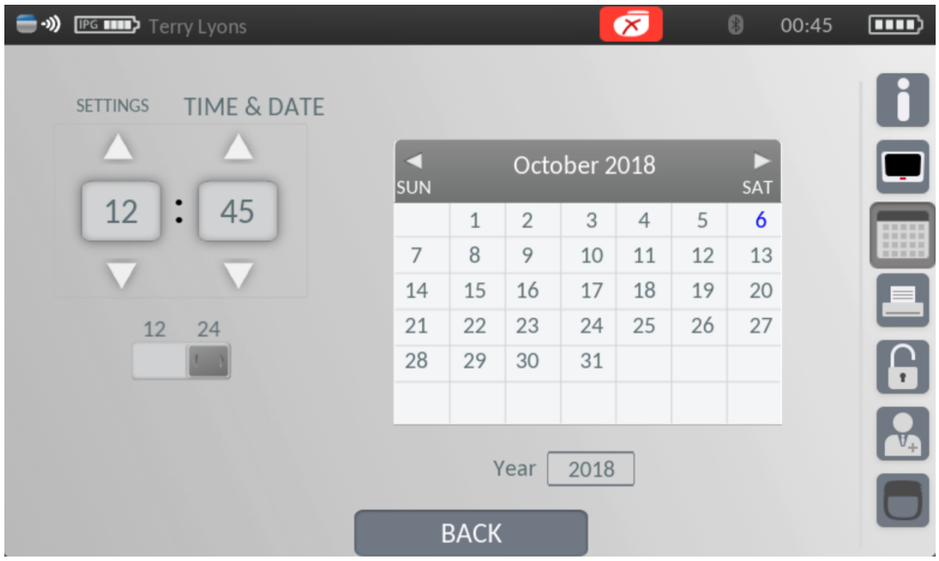
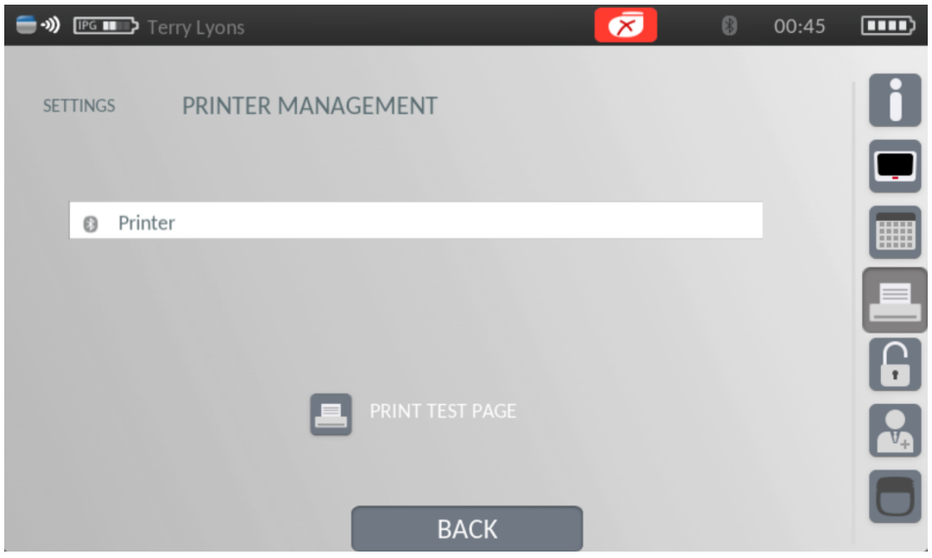
Time & Date



Calendar	Tap a day to set the month and day.
Year	Tap to enter a year.
Hour & Minute	Tap to change the hour and minute.
12/24	Tap the arrows to set the display of time to a 12-hour or 24-hour clock.
AM/PM	Tap the arrows to set the time to AM or PM. Displays when 12/24 is set to 12.

Printer Management



	Tap to print a test page to troubleshoot issues with the printer. Make sure to turn on the printer and to move the printer in range of the Clinician Programmer prior to printing a test page.

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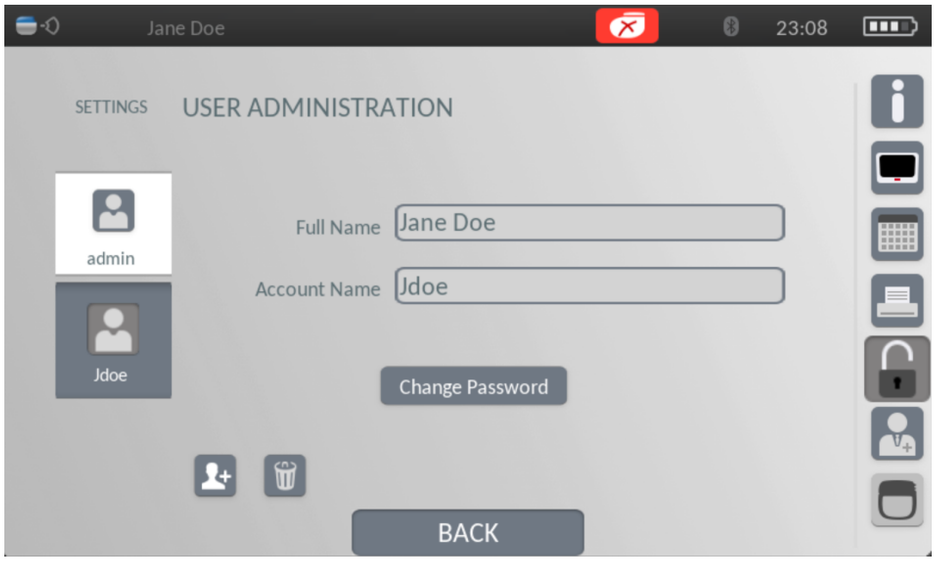
User Administration



Change Password	Tap to change the selected user's password. **Note**: An Admin user can change the password for any user. Users can change only their passwords.
	Tap to add a user. **Note**: Only the Admin user can add a user.
	Tap to delete a user. **Note**: Only the Admin user can delete a user.

Physician Administration

Physician's Name	Tap to edit the information for the physician. Scroll to view additional physicians.
	Tap to add a physician. The required fields are First Name, Last Name, and Practice.
	Tap to delete a physician. Deleting a physician removes the physician from all patients.

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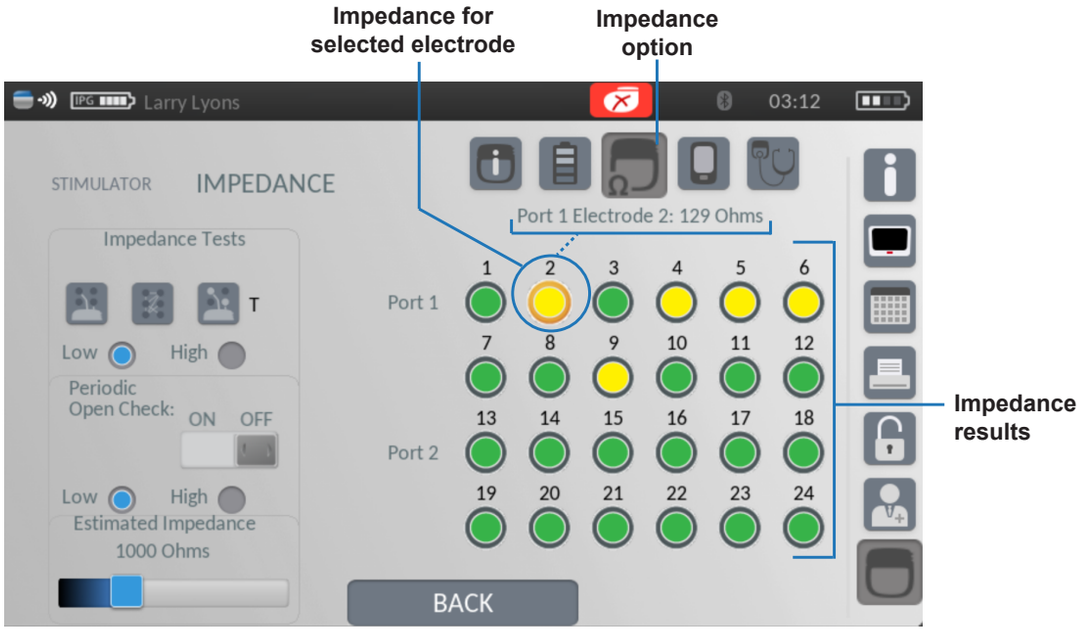
Battery & ERI

Battery Charges	The number of full battery charges of the stimulator.
Storage Mode Exits	The number of times the stimulator exited storage mode.
Battery Depletions	The number of times the stimulator battery depleted.
Implantation	The date when the stimulator was implanted.
ERI Expiration	The expected replacement date of the stimulator, which is ten years from the implant date.

Advanced Impedance Checks



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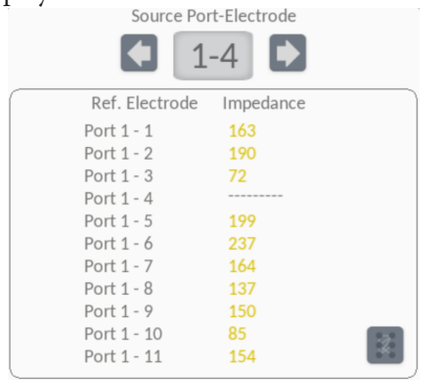
Impedance Tests: Low/High	Tap to set the amplitude at which the stimulator executes the impedance check; the default for Low is 0.1 milliamps and High is 0.2 milliamps. Execute an initial impedance check using the low setting. Contact Aleva Customer Service when results indicate low impedance or high impedance and you cannot find an efficient treatment for a patient. **Impedance Test Options** • Tap to check the impedance between each electrode and the can or ground pad (when using a trial stimulator). The impedance results display in Impedance History. • Tap to check the impedance between a selected electrode and the other electrodes. The inpedance results display on the screen.  • Tap to check the impedance between configured electrodes in the most recently viewed configuration or program and the can or ground pad (when using a trial stimulator). **Note:** When running an impedance check after viewing a configuration in the Therapy task, a **T** displays next to . When running an impedance check after selecting a program on the Manage Programs, a program identifier (P1–P4) displays next to . **Impedance History** Results for and display in Impedance History: » – Impedance not tested » – Low impedance (≤ 250 ohms) » – Normal impedance (250–9000 ohms) » – High impedance (> 9000 ohms) Tap an electrode in Impedance History after running an impedance check to view its impedance. Refer to *Reports on page 41* for instructions on adding impedance check results to the patient report.
Periodic Open Check	When turned on, the stimulator checks impedance of the electrodes configured for the running program each time stimulation starts and stops, and periodically while stimulation is on. When electrodes with low impedence are detected, the stimulator disables all programs using these electrodes. When turned on, set the amplitude for the background impedance checks; Low is 0.1 milliamps (default) and High is 0.2 milliamps. **Note:** Both open and short impedance measurements use the same amplitude settings.
Estimated Impedance	This is an advanced feature. The default is 1000 Ohms. Contact Aleva Customer Service for more information.

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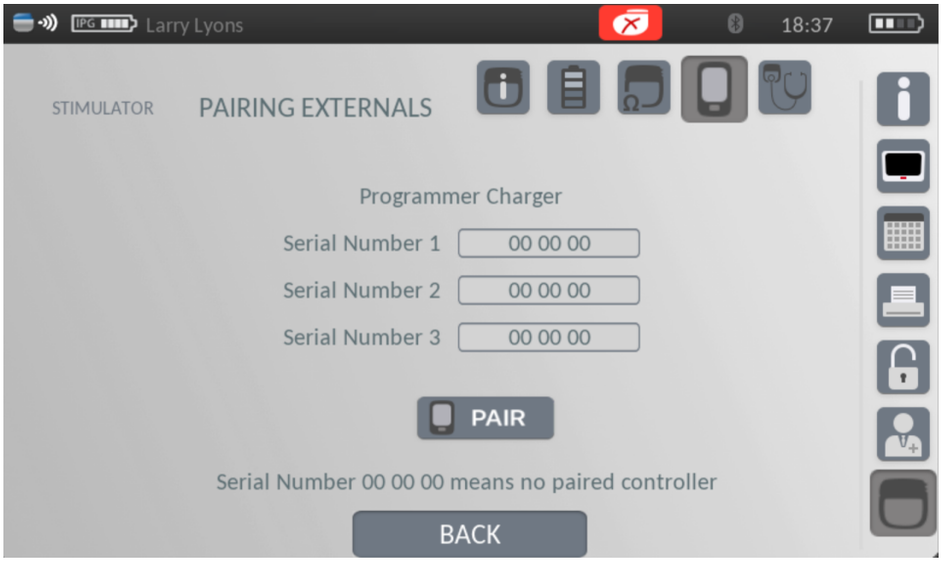
Patient Programmer Charger Pairing

Clinicians can pair up to three Patient Programmer Chargers with a stimulator. The Patient Programmer Chargers are not needed during pairing.

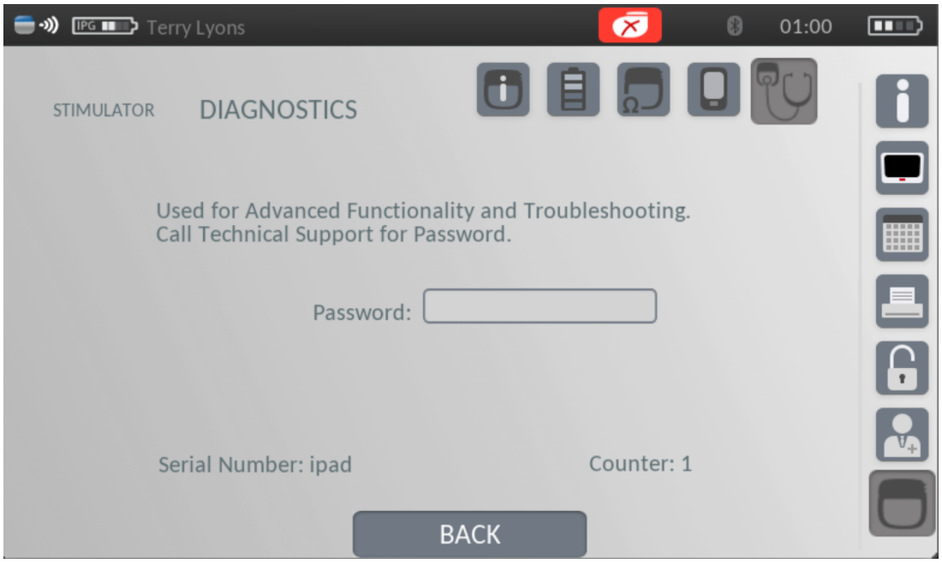


To pair external devices with a stimulator:

1. Enter a serial number for each Patient Programmer Charger issued to a patient. The serial number is located on a label on the back of a Patient Programmer Charger.
2. Tap PAIR to pair the Patient Programmer Chargers matching the entered serial numbers with a stimulator.

Diagnostics

Access diagnostic information when requested by Aleva Customer Service.



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10. Reports

The Report option on the Patient List screen gives the clinician the ability to create and print a patient report on a Zebra EM220 strip printer or a compatible replacement.

To view and print a report:

1. Move the printer that is powered on to within 1 meter of the Clinician Programmer.
2. Tap a patient in the patient list, and then tap .
   General information about the patient and their stimulator displays.
3. Tap one or more report options to add information to the displayed report.
4. Tap to print the report.

	Tap to view Clinician Programmer and patient information. This information displays on every report.
	Tap to add information about the stimulator, paired Patient Programmer Chargers, Magnet Mode setting, and lead-to-port connections.
	Tap to add information such as the implant date and the charge density of electrodes.
	Tap to add program information such as the originator, run time, electrode configuration, and stimulation settings.
	Tap to add the patient's physician.
	Tap to add the Open Circuit Check setting and the results of the most recent impedance check.
	Tap to add the Clinician Programmer battery information, Storage Mode setting, and diagnostic messages.

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11. Charging the Clinician Programmer Battery

The Clinician Programmer battery status displays in the status bar of the Clinician Programmer. Refer to *Using the Status Bar on page 3*.

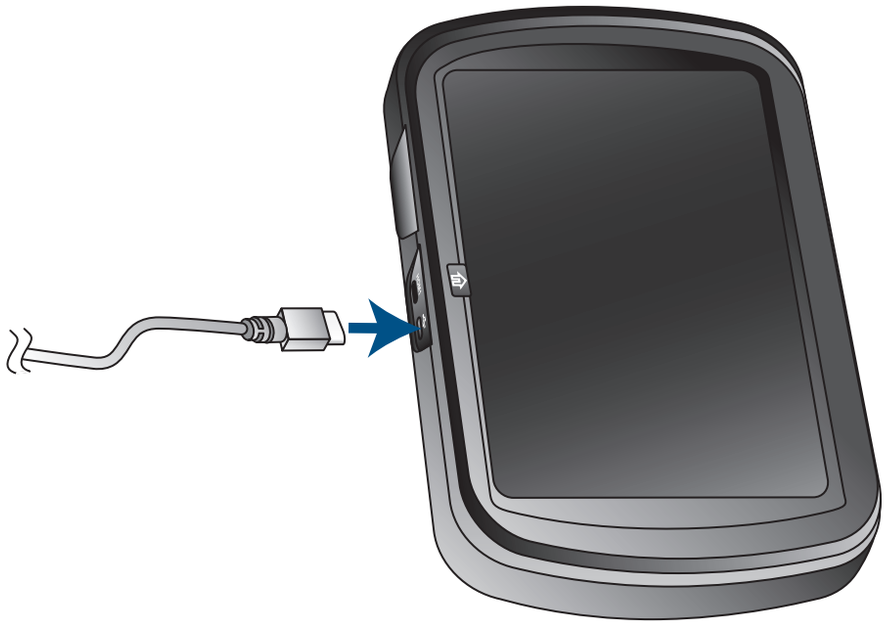
If storing the Clinician Programmer for an extended period of time, fully charge the Clinician Programmer, then charge the Clinician Programmer every six months. The Clinician Programmer uses a small amount of charge while off and may become non-rechargeable if not periodically charged.

If the Clinician Programmer charge drops below 15%, the Clinician Programmer stops stimulation initiated during program configuration. If the Clinician Programmer shuts down from a low charge, connect the Clinician Programmer to the power cord and restart the programmer (refer to *Turning the Clinician Programmer On and Off on page 3).* If you were programming when the Clinician Program shut down, view programs to verify they are complete.

Note: You can use the Clinician Programmer while it is charging.

To charge the Clinician Programmer:

- Insert the power cord into the micro USB port on the bottom of the Clinician Programmer.



For more information about the power cord, see the instructions packaged with the Power Cord Model 12340.

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12. Care, Handling, and Disposal

Care and Handling

Handle the directSTIM DBS System components and accessories with care. Do not drop them or submerge them in water. Avoid all sources of water that can come into contact with the devices. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components.

Cleaning the Clinician Programmer

The Clinician Programmer and power cord are not waterproof. Do not immerse them in liquid or allow moisture to get inside the cases.

If the Clinician Programmer is dirty, clean the outside with a slightly damp cloth. Do not clean your Clinician Programmer with bleach, nail polish remover, or similar substances.

Clean the Clinician Programmer screen with a household glass cleaner that does not contain ammonia.

Storing the Clinician Programmer

Caution: If you store the Clinician Programmer for an extended period of time, make sure to fully charge the battery before storing, and periodically charge the battery every 6 months. The Clinician Programmer uses a very small amount of battery charge while turned off and may become non-rechargeable if not periodically charged.

The sensitive electronics of the Clinician Programmer can be damaged by temperature extremes, particularly high heat.

- Do not expose the Clinician Programmer to excessively hot or cold conditions, including leaving the Clinician Programmer in your car or outdoors for extended periods of time.
- If storing the Clinician Programmer for an extended period of time, the temperature should not exceed -20°C to 60°C.

Repairing the Clinician Programmer

The Clinician Programmer does not have any user-serviceable parts. Do not attempt to open or repair the device. Unauthorized repairs will void the warranty. If unforeseen service is required, only Aleva should service or repair the Clinician Programmer.

If you have any questions about a directSTIM DBS System, call Aleva Customer Service at +41 21 353 87 64.

When contacting Aleva, have the Clinician Programmer serial number available, which is located on the label on the back of the device.

Disposing a Clinician Programmer

The Clinician Programmer contains rechargeable lithium batteries. Do not incinerate or dispose of the Clinician Programmer in general household trash. When no longer needed, return the Clinician Programmer to Aleva or consult local regulations for proper disposal of electronic devices.

Cleaning the Trial Stimulator

Inspect the trial stimulator for dirt, debris or residue. If needed, clean the trial stimulator.

1. Follow your healthcare facility procedures for the cleaning of medical devices. If your healthcare facility does not have a cleaning procedure, clean with hospital-grade isopropyl alcohol (IPA).
2. As needed, clean the trial stimulator battery contacts with a cotton swab dampened with alcohol.

   Note: Do not use a pencil eraser or sandpaper to clean the battery contacts.
3. Before using the trial stimulator, make sure it is dry.

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Storing the Trial Stimulator

Extreme temperatures, particularly high heat, can damage the sensitive electronics of the trial stimulator.

- Do not expose the trial stimulator to excessively hot or cold conditions, including leaving the trial stimulator in your car or outdoors for extended periods of time.
- If the trial stimulator is to be stored for an extended period of time, the temperature should not exceed -20°C to 60°C.

Repairing the Trial Stimulator

The trial stimulator does not have any user-serviceable parts. Do not attempt to open or repair the device. Unauthorized repairs will void the warranty. If unforeseen service is required, only Aleva should service or repair the trial stimulator.

If you have any questions about a directSTIM DBS System, call Aleva Customer Service at +41 21 353 87 64.

When contacting Aleva, have the trial stimulator serial numbers available, which is located on the label on the back of the device.

Disposing a Trial Stimulator

In case the trial stimulator is not returned to Aleva, consult local regulations for proper disposal of AAA batteries and electronic devices.

Return explanted leads, extensions, and anchors to Aleva. Do not autoclave the components or expose them to ultrasonic cleaning. Dispose of unreturned components according to local environmental regulations.

Replacing Accessories

Contact Aleva if you lose a power cord or other accessory.

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13. Troubleshooting

If the instructions in this chapter do not solve your problem, contact Aleva Customer Service.

Aleva Customer Service

If you have any questions about the directSTIM DBS System, call your product distributor for assistance. If additional assistance is needed, contact Aleva Customer Service at +41 21 353 87 64.

Clinician Programmer Troubleshooting

Problem	Possible Cause and Solution
Patient is not experiencing stimulation.	The Clinician Programmer is not connected to the stimulator. **Disconnect the stimulator from any nearby Patient Programmer Chargers or Clinician Programmers, then tap in the status bar to establish a connection.**
	The impedance at the stimulation site increased. **Conduct an impedance test and review the results. If necessary, adjust the estimated impedance. Refer to** *Advanced Impedance Checks on page 38.*
	The stimulator has disabled a program. **Run an impedance check. Refer to** *Advanced Impedance Checks on page 38.* **Contact Aleva Customer Service for additional assistance.**
Cannot start stimulation. **Stimulation stopped unexpectedly.** **The Clinician Programmer does not turn on.**	The battery of the Clinician Programmer is too low. **Charge the Clinician Programmer. Refer to** *Charging the Clinician Programmer Battery on page 43.* *- or -* **If you continue to struggle recharging your Clinician Programmer, contact Aleva Customer Service to identify if a replacement component is needed.**
After tapping an icon, nothing happens.	The Clinician Programmer touch screen is out of calibration. **Calibrate the touch screen. Refer to** *Display on page 35.*
Cannot increase or decrease parameters for a program.	Increasing or decreasing the parameter is outside the allowed range.
	An anode or cathode is not specified. **When stimulation polarity is set to bipolar for a lead, select an anode row of electrodes and at least one cathode row of electrodes. Refer to** *Configuring Stimulation on page 21.*
The programs on the stimulator (visible via the Patient Programmer Charger) do not display on the Clinician Programmer.	Patient information and programs are not synchronized. **Import patient information and programs from the stimulator to the Clinician Programmer. Refer to** *Adding a Patient on page 10.*
Cannot start stimulation for a program in the Manage Programs task.	Patient information and programs are not synchronized. **Synchronize patient information and programs on the Clinician Programmer with the stimulator. Refer to** *Manage Programs Task on page 27.*
A program has stopped.	The stimulator has disabled a program. **Execute an impedance check and review the results. Refer to** *Advanced Impedance Checks on page 38.*
Cannot change the amplitude on an electrode.	The electrode is locked. **Change the electrode configuration. Refer to** *Using the Therapy Task Screen on page 18.*
Implant date is incorrect.	The wrong date was assigned. **Contact Aleva Customer Service to change the implant date.**
Trouble communicating with a stimulator.	Environmental conditions for the stimulator changed. **Autotune the stimulator. Refer to** *Settings on page 33.*
Stimulation does not turn on with a magnet.	Magnet mode is off. **Turn magnet mode on. Refer to** *Settings on page 33.*

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Problem	Possible Cause and Solution
Cannot connect to a stimulator.	Stimulator is in Storage Mode. **Start charging the stimulator with the Patient Programmer Charger. This action takes the stimulator out of Storage Mode. Refer to the Patient System Manual for instructions.**

Clinician Programmer Messages

Some messages may include a reference number. If provided, note the reference number when contacting Aleva Customer Service.

Message	Description/Possible Action
Unable to communicate with stimulator. Try again.	Verify the stimulator is within range of the Clinician Programmer. Reconnect by tapping in the status bar.
Unable to proceed. Verify the stimulator is on, within range, and not connected to another Clinician Programmer or Patient Programmer Charger.	
Unable to create patient record from stimulator. Create patient record manually.	
Unable to communicate with stimulator. Manually push programs when able to connect.	
Unable to connect. Clinician Programmer battery too low.	Plug the power cord into the Clinician Programmer to ensure uninterrupted usage.
Battery level is at 10%. Charge Clinician Programmer.	
An existing patient record is associated with the selected stimulator.	The Clinician Programmer contains a patient with the same stimulator serial number.
That stimulator already exists on this CP. Use it anyway?	
Unable to push programs to the stimulator.	Delete all programs from the Clinician Programmer in the "Manage Programs" screen. Pull programs from patient's stimulator. Then create a new program or edit an existing program, and re-enter the new stimulation parameters that were planned for the chosen program and save the program in an empty slot. Do not use the "replace" button. Erase the previous program if you don't want to make it available in the Patienatient Programmer Charger.
The model type in the patient record does not match the model type for the stimulator.	Verify the model and serial number for the patient.
Unable to clear data from the trial stimulator. Manually clear data before reusing.	Clear the data from the stimulator by tapping on the General stimulator settings screen. Refer to *Settings on page 33.*
Stimulator programs do not match Clinician Programmer programs.	Synchronize patient information and programs with the stimulator.

Caution when replacing an existing Program

In the event that modifications are made to a program that had pre-existing scoring data, the REPLACE button should not be used, because it would result in the unwanted replacement of some stimulation values by null values. It is important to underline that, in such event, no program parameters can be pushed to the IPG, thus protecting the programs in the IPG.

In such event, the User should:

- Delete all programs from the CP in the "Manage Programs" screen, and then pull the programs from the IPG back into the CP.
- Then re-enter the new stimulation parameters that were planned for the chosen program and save it in an empty slot (as described in the Save a Program section on page 26)
- Once the programs in the IPG have been pulled back into the CP, the IPG can be started using the CP. At any time, the IPG can be started using a Patient Programmer and Charger.

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Charging a Fully Discharged Implantable Stimulator

A patient may need assistance to charge a fully discharged implantable stimulator.

To charge a fully discharged implantable stimulator:

1. Move the Patient Programmer Charger within 1 meter of the implantable stimulator and turn on the Patient Programmer Charger. The Not Able to Connect screen displays.
2. Tap **Cancel** to display the Home screen.
3. Connect the charging paddle to the Patient Programmer Charger.
4. Align the charging paddle over the implantable stimulator. Use an adhesive patch to hold the charging paddle in place.
5. Tap . The Charge Status screen displays.
6. Tap **OK** on the Charge Status screen.
7. Wait until charging completes.
8. Tap **OK** on the Charging Complete screen.
9. Tap to connect to the implantable stimulator.

Setting the Implantable Stimulator Depth

Adjust the depth setting if an implantable stimulator is implanted deeper than 1.5 cm or if the patient has trouble charging the implantable stimulator.

To set the implant depth:

1. Tap on the Home screen of the Patient Programmer Charger.
2. Tap **Advanced Settings** on the Programmer Settings screen.
3. Enter the last two digits of the serial number located on the back of the Programmer Charger, and tap **OK**.
4. Tap **Implant Depth** on the Advanced Settings screen.
5. Select **Deep**.

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14. System Specifications

Component Specifications

If you have any questions regarding this information, contact Aleva Customer Service.

Clinician Programmer Specifications	
Operating temperature	0° C to 40° C
Operating humidity	10% to 95%
Storage temperature	-20° C to 60° C
Storage humidity	10% to 85%
Operating/storage atmospheric pressure	70 kPa to 106 kPa
Size (approximate)	213.4 x 127 x 23 mm
Weight including battery (approximate)	450 grams
Battery	Rechargeable lithium-ion battery
Mode of operation	Continuous

Trial Stimulator Specifications	
Operating temperature	10° C to 40° C
Operating humidity	10% to 95%
Storage temperature	-20° C to 60° C
Storage humidity	10% to 85%
Operating/storage atmospheric pressure	70 kPa to 106 kPa
Size (approximate)	5.1 cm x 8.6 cm
Weight including battery (approximate)	73.5 grams
Battery	2 AAA Alkaline battery 1.5v
Mode of operation	Continuous

Trial Stimulator Component Materials

Component Materials in Contact with Tissue	
Trial Stimulator	Acrylonitrile butadiene styrene Polycarbonate

Safety and Compatibility Standards Conformity

The directSTIM DBS System Clinician Programmer Model 12200 and Trial Stimulator Model 12400 comply with the following standards:

- IEC 60601-1, Medical Electrical Equipment Safety
- IEC 60601-1-2, Electromagnetic Compatibility
- ISO 14708-1, Safety, Marking and Information of Medical Devices

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Electromagnetic Compatibility

The Federal Communications Commission (FCC) and various international agencies have rules and regulations meant to minimize interference created by electronic devices.

The Clinician Programmer and Trial Stimulator meet U.S. and European regulatory limits for Electromagnetic Compatibility (EMC). EMC is the ability of electronic devices, including computers, to function properly together in the electronic environment. However, there is no guarantee, depending on the specific circumstances, that the Clinician Programmer or Trial Stimulator will not interfere with other electronic devices. Should the Clinician Programmer or Trial Stimulator cause harmful interference to radio or television reception, which can be determined by turning the Clinician Programmer or Trial Stimulator off and on, you are encouraged to try to correct the interference by doing the following:

- Relocate the Clinician Programmer or Trial Stimulator away from the affected electronic device

Electromagnetic Compatibility Declaration Tables

This section lists the EMC Declaration tables for the directSTIM DBS System Clinician Programmer and Trial Stimulator. The Clinician Programmer and Trial Stimulator are intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer or Trial Stimulator should assure that it is used in such an environment. The Clinician Programmer and Trial Stimulator contain RF transmission and receiving capabilities; consequently, it is possible that other portable and mobile RF communications equipment may interfere with the Clinician Programmer or Trial Stimulator.

The approved power supply cable used with the Clinician Programmer and the trial cable and ground pad used with the Trial Stimulator were included in the directSTIM DBS System testing to demonstrate compliance with the requirements of IEC 60601-1-2:2014. Use of accessories and cables other than those specifically listed may result in increased emissions or decreased immunity of the Clinician Programmer or Trial Stimulator.

The Clinician Programmer or Trial Stimulator should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Clinician Programmer should be observed to verify normal operation in the configuration in which it will be used. The essential performance of the Clinician Programmer or Trial Stimulator is that it cannot cause the stimulator to exceed stimulation limits set by the clinician.

Guidance and manufacturer's declaration for the Clinician Programmer and Trial Stimulator - electromagnetic emissions		
The Clinician Programmer and Trial Stimulator are intended for use in a professional healthcare facility electromagnetic environment and are compliant with the limits specified below. The customer or the user of the Clinician Programmer or Trial Stimulator should assure that they are used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Clinician Programmer and Trial Stimulator use RF energy primarily for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Clinician Programmer is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The Trial Stimulator is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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Guidance and manufacturer's declaration for the Clinician Programmer - electromagnetic immunity			
The Clinician Programmer is intended for use in a professional healthcare facility electromagnetic environment and is compliant with the limits specified below. The customer or the user of the Clinician Programmer should assure that they are used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Clinician Programmer requires continuous operation during power mains interruptions, it is recommended that the Clinician Programmer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Notes: U_T is the A.C. mains voltage before application of the test level.			

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Guidance and manufacturer's declaration for the Trial Stimulator - electromagnetic immunity			
The Trial Stimulator is intended for use in a professional healthcare facility electromagnetic environment and is compliant with the limits specified below. The customer or the user of the Trial Stimulator should assure that they are used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable - Battery powered device
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable - Battery powered device
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Not applicable	Not applicable - Battery powered device
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Notes: U_T is the A.C. mains voltage before application of the test level.			

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Guidance and manufacturer's declaration for the Clinician Programmer - electromagnetic immunity			
The Clinician Programmer is intended for use in a professional healthcare facility electromagnetic environment and is compliant with the limits specified below. The customer or the user of the Clinician Programmer should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Proximity Fields from RF wireless communication equipment IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz Per table 9 of §8.10 9 to 28 V/m 385 MHz to 5785 MHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 6 GHz 9 to 28 V/m 385 MHz to 5785 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Clinician Programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\ \sqrt{P}$ $d=1.2\ \sqrt{P}$ 80 MHz to 800 MHz $d= 2.3\ \sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Clinician Programmer is used exceeds the applicable RF compliance level above, the Clinician Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Clinician Programmer. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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Guidance and manufacturer's declaration for the Trial Stimulator - electromagnetic immunity			
The Trial Stimulator is intended for use in a professional healthcare facility electromagnetic environment and is compliant with the limits specified below. The customer or the user of the Trial Stimulator should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Trial Stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance Not applicable - battery powered
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 6 GHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b]
Proximity Fields from RF wireless communication equipment IEC 61000-4-3	Per table 9 of §8.10 9 to 28 V/m 385 MHz to 5785 MHz	9 to 28 V/m 385 MHz to 5785 MHz	Recommended separation distance: $E = 6/d*\sqrt{P}$ Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Clinician Programmer is used exceeds the applicable RF compliance level above, the Clinician Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Clinician Programmer. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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Recommended separation distances between portable and mobile RF communications equipment and the Clinician Programmer or Trial Stimulator			
The Clinician Programmer and Trial Stimulator are intended for use in a professional healthcare facility electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Clinician Programmer and Trial Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Clinician Programmer and Trial Stimulator as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz $d=1.2\sqrt{P}$**	**800 MHz to 2.7 GHz $d=2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Wireless Information

Wireless Specifications and Safety	
Programmer wireless technology operating characteristics	The Clinician Programmer interacts with the stimulator using MedRadio Band: 402-405 MHz. The effective radiated power is below the limits as specified in: Europe: Radio Equipment Directive 2014/53/EU USA: FCC 47 CFR Part 95
	The Clinician Programmer interacts with the stimulator using 2.45 GHz. The effective radiated power is below the limits as specified in: Europe: Radio Equipment Directive 2014/53/EU USA: FCC 47 CFR Part 15
Stimulator wireless technology	The stimulator complies with emissions requirements per Radio Equipment Directive 2014/53/EU (402 MHz to 405 MHz).
Wireless integrity	The directSTIM DBS System employs mechanisms to ensure integrity of the communication area. The stimulator will not respond to any device to which it is not linked.

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Compliance and Authorizations for the Clinician Programmer

The Clinician Programmer has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area may cause harmful interference in which case the user will be required to correct the interference at his own expense.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary bases in the 2360-2400 MHz band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmissions from this transmitter will be free from interference.

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15. Glossary

Term	Definition
balancing	The automatic allocation of the total amplitude for a polarity of a program to equal 100%.
beneficial effect score	Indications of stimulation effects.
Effect Boards	Displays the saved collection of therapeutic windows.
electrode row	Electrodes of a lead that are at the same distal distance.
EPG	External Pulse Generator. Also known as the trial stimulator.
IPG	Implantable Pulse Generator. Also known as the implantable stimulator.
Patient Programmer Charger	A patient programmer used to adjust stimulation. Includes a charging paddle to charge the implantable stimulator.
program	A combination of the electrode configuration, stimulation parameter settings, stimulation polarity, and optional scoring.
side-effect score	Stimulation settings that cause a patient to experience a side effect.
step	The rate of increase or decrease when adjusting amplitude.
therapeutic window	The amplitude range between a beneficial effect score and a side-effect score.

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Aleva Neurotherapeutics SA
EPFL Innovation Park, Building D
1015 Lausanne, SWITZERLAND
+41 21 353 87 64
customer@aleva-neuro.com

EC REP
Medidee Services GmbH
Hohnenweg 9
78098 Triberg
GERMANY
+49 173 65 99 215

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PR-12200 Rev F

2022-09