Evoke® SCS System Clarity™ Clinical Manual

Use of the Evoke Clinical Interface (CI) and Clarity Programming Application (CPA) with the Evoke Clinical System Transceiver (CST) for programming the Evoke SCS System

Rx Only

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Trademarks

Refer to the Evoke SCS System Surgical Guide for:

- System warnings and precautions
- Instructions on the implantation of the Evoke System components
- Other system component device specifications and package contents

Refer to the Evoke SCS System User Manual for:

- Instructions on the use of the Evoke Patient Controller (EPC), Magnet, Accessory Belt and Evoke Charger.

Manuals are accessible at http://www.saludamedical.com/manuals.

1. Description

The Saluda® Medical Evoke® SCS System is a Spinal Cord Stimulation (SCS) system that incorporates ECAP-controlled closed-loop stimulation for the management of chronic, intractable pain. The Evoke System measures evoked compound action potentials (ECAPs) and may be programmed to deliver either ECAP-controlled closed-loop SCS or fixed-output open-loop SCS.

The Evoke Clinical Interface (CI) and Evoke Clinical System Transceiver (CST) enable the programming of the implantable Closed-Loop Stimulator (CLS) and the non-implantable External Closed-Loop Stimulator (eCLS).

The Evoke System may be used in conjunction with other pain management therapies, as determined by the physician.

1.1 The concept of ECAP-controlled closed-loop SCS

The Evoke System uses ECAP amplitude to measure the patient's neural response and provide closed-loop (CL) SCS. The ECAP amplitude is a measure of the spinal cord activation or number of dorsal column fibers in the spinal cord that are activated by a stimulation pulse. When closed-loop (feedback) is enabled, the system automatically varies the stimulation current for every pulse to maintain consistent spinal cord activation during physiological changes and movement.

Figure 1.1, below, depicts the concept of an ECAP-controlled closed-loop system. Following a stimulation pulse, the amplitude of the ECAP that is generated in the spinal cord by that stimulus is recorded. The ECAP amplitude is compared to the selected target and then used to automatically adjust the current of the next stimulus to maintain a consistent ECAP amplitude.
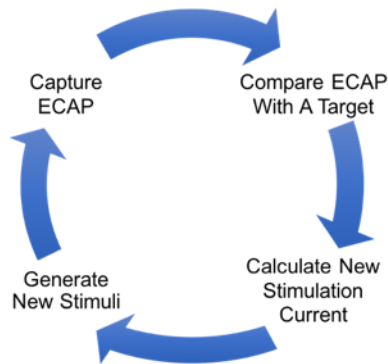

Figure 1.1: ECAP-Controlled Closed-Loop SCS.

1.2 Stimulation Features

The Evoke System provides the following advanced stimulation options.

1.2.1   Closed-loop SCS

When closed-loop is enabled, the system uses feedback of the ECAP amplitude to automatically adjust the stimulation current of every pulse to maintain a target activation level. This ensures consistent dorsal column activation during physiological changes and movement.

1.2.2   Open-loop SCS

When closed-loop is disabled, the system delivers a fixed-output of stimulation current, while continuing to measure ECAP amplitude. Since the stimulation current is fixed, the activation level will vary as the spinal cord moves relative to the stimulation electrodes.

1.2.3   Current steering

Multiple stimulation electrodes can be used simultaneously, with a scaled portion of the total current delivered to each electrode. This enables more targeted stimulation between electrodes.

1.2.4   Interleaved stimulation

Two or more stimulation configurations can be used concurrently, with the system automatically cycling through each configuration. Each interleaved configuration (Stim-Set) can target a different area of the patient's pain.

1.2.5   Stimulation Waveform

Each stimulation waveform consists of constant current, actively charge-balanced, pulses. The output current is automatically controlled when closed-loop is enabled and set to a fixed level when closed-loop is disabled. The stimulation waveform can be customized (see Figure 1.1 for example) by the selection of the following parameters: pulse shape, polarity, stimulation current, and pulse timing.
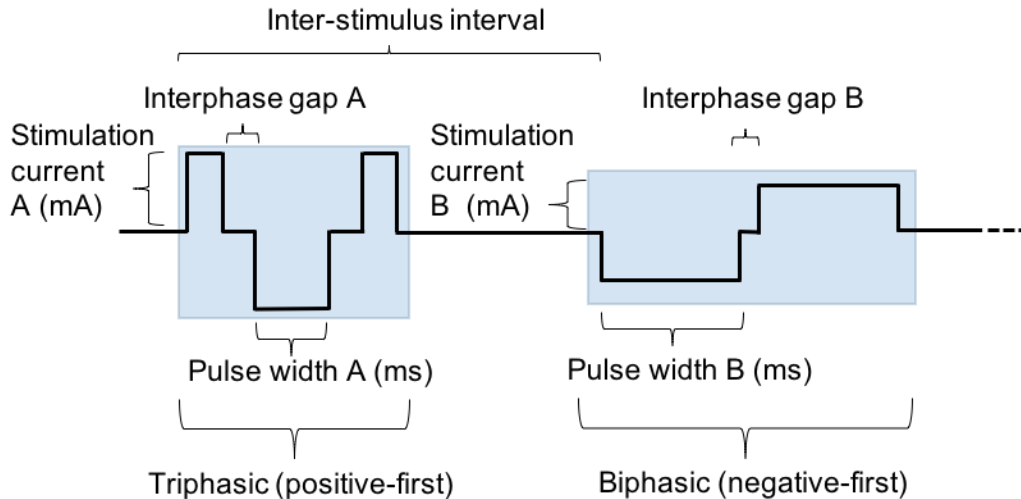
Figure 1.2: Example stimulation waveform for a program with two Stim-Sets. Stim-Set A is shown with triphasic and positive-first, and Stim-Set B is shown with biphasic and negative-first. Each Stim-Set may also have a different stimulation current, pulse width, and interphase gap. The inter-stimulus interval is configurable for each program.

1.2.5.1 *Pulse shape and polarity*

Each pulse can be configured to have two (biphasic) or three (triphasic) phases, and to either start with a positive phase (positive-first) or negative phase (negative-first). The pulse shape and polarity can be customized for each Stim-Set (see Section 6.4.4 to set the pulse shape and polarity, and Figure 1.2 for examples).

1.2.5.2 *Stimulation current*

When closed-loop is disabled, the stimulation current is fixed at the level chosen by the user (see Section 6.4.4). When closed-loop is enabled, the stimulation current is automatically adjusted in response to the difference between the ECAP amplitude and the target level chosen by the user. The stimulation current can be customized for each Stim-Set, such that the ratio of stimulation currents between each Stim-Set is kept constant.

1.2.5.3 *Pulse width*

With a biphasic pulse, the pulse width sets the duration of each phase. With a triphasic pulse, the pulse width sets the duration of the second phase, which is equal to the sum of the durations of the first and third phase. The pulse width can be customized for each Stim-Set (see Section 6.4.4).

1.2.5.4 *Interphase gap*

The interphase gap is a pause between each phase when no current is delivered (e.g. Figure 1.2). The interphase gap can be customized for each Stim-Set (see Section 6.4.4).

1.2.5.5 *Inter-stimulus interval*

In programs with 2 to 4 Stim-Sets (see Section 6.4.4.2), the inter-stimulus interval sets the time between the start of the pulses from one Stim-Set and the start of the next Stim-Set (e.g. Figure 1.2). The inter-stimulus interval can be customized for each program (see Section 6.4.4). In programs with one Stim-Set, this parameter is not used.

1.2.5.6 *Stimulation Frequency*

Each stimulation waveform as defined by the above parameters (e.g. Figure 1.2.) repeats at a set frequency. The stimulation frequency can be customized for each program (see Section 6.4.4).

1.3 Measurement Features

The Evoke System supports the following types of measurements and data analysis. Refer to the Evoke SCS System RECAP Viewer User Manual for additional information on data analysis.

1.3.1 ECAP Measurements

ECAP amplitude is a measure of spinal cord activation and is used by the stimulator for closed-loop stimulation. ECAP signals can be viewed in the CPA during a programming session (to objectively observe the patient's neural response, independent of the patient's subjective reports), and also later analyzed in the RECAP Viewer for their objective features (such as shape, latency, conduction velocity and amplitude).

1.3.2 ClearCAP™

ClearCAP is used to reduce the artefact recorded during measurement by cancelling the artefact from the stimulation and return electrodes; this feature is best used when optimizing ECAP measurement (see Section 6.4.5).

1.3.3 Therapeutic window

During a programming session, the CPA may be used to record the ECAP amplitude at the patient's threshold, comfort and maximum levels, which may then be used to define the patient's therapeutic window.

1.3.4 Detection of late response

Late responses are neural responses resulting from dorsal root activation. Late responses have longer latency than ECAPs and they do not propagate along the spinal cord. They can be viewed in the CPA during a programming session or reviewed later in the RECAP Viewer.

1.3.5 Activation Plot and Sensitivity

The CPA displays a plot of activation (ECAP amplitude) as a function of stimulus current for one or more postures. The sensitivity of a patient's neural response to changes in stimulation current can be measured from the slope of the activation plot.

1.3.6   Data recording and patient compliance

While the patient is using their stimulator, various usage and measurement data are recorded on the stimulator. This data includes stimulation status (on/off), closed-loop status (enabled/disabled), ECAP amplitude, stimulation current, and patient interactions with the device. This data is downloaded via the CPA and can be viewed in the RECAP Viewer.

1.3.7   Neural response profile (NRP)

The neural response profile is a set of objective measures characterizing the spinal cord activation levels experienced by the patient while using their stimulator. Activation level (ECAP amplitude) is continuously recorded and compressed into histogram bins on the stimulator for later analysis on the RECAP Viewer.

1.3.8   Conduction velocity (CV)

ECAP recordings can be used to determine the conduction velocity of the dorsal column fibers being stimulated. ECAPs are recorded using the CPA and analyzed using the RECAP Viewer to calculate their velocity. Changes in the population of fiber sizes activated and fiber properties may be detected through changes in CV.

1.3.9   Chronaxie and rheobase (strength-duration curve)

ECAP amplitudes recorded at different stimulation pulse widths can be used to objectively calculate chronaxie and rheobase for fibers activated during spinal cord stimulation. Changes in axonal excitability or distance from electrode may be detected through changes in chronaxie or rheobase.

1.3.10 Lead offset

The vertical alignment of two implanted leads may be estimated using the lead offset check feature in the CPA. The offset between two leads may be used to guide the choice of stimulation and measurement electrodes.

1.4 System Components

1.4.1   Evoke Closed-Loop Stimulator (CLS)

Ref No. 3042

The Evoke Closed-Loop Stimulator (CLS) is a totally implanted spinal cord stimulator that connects to the CAP12 Percutaneous Leads and is implanted under the skin for long-term therapy. The CLS delivers either closed-loop or open-loop stimulation through the leads and measures the neural response to stimulation. A port plug is provided with the CLS, for insertion into an unused CLS port when only one lead is implanted.

1.4.2   Evoke External Closed-Loop Stimulator (eCLS)

Ref No. 3036

During the trial stimulation period, the CAP12 Percutaneous Leads are connected to the Evoke External Closed-Loop Stimulator (eCLS). The eCLS is an external stimulator used for intraoperative testing and during the trial stimulation period. The eCLS delivers either closed-loop or open-loop stimulation through the leads and measures the neural response to stimulation.

1.4.3   Evoke eCLS Case

Ref No. 3035

The Evoke eCLS Case is used by the patient to house the eCLS during the trial stimulation period. The kit also includes two lead adapters to connect the leads or lead extensions to the eCLS.

1.4.4   Evoke CAP12 Percutaneous Lead Kit, 60cm and 90cm

Ref No. 3008/3016/3009/3017

The Evoke CAP12 Percutaneous Leads are placed in the epidural space overlying the spinal cord and are connected to an eCLS for a trial stimulation period, or to a CLS for long-term therapy. One or two leads, each with 12 electrodes, are implanted. The lead kit is provided with one suture anchor to secure the lead, and surgical accessories (epidural needle and two stylets) for use during lead placement.

1.4.5   Evoke CAP12X Lead Extension Kit, 55cm

Ref No. 3011

The Evoke CAP12X Lead Extensions are required when the implanted lead does not reach the CLS pocket, or when trialing a permanently implanted lead, when an extension is externalized for connection to an eCLS.

1.4.6   Evoke Active Anchor Kit

Ref No. 3043

The Evoke Active Anchor allows the surgeon to secure the lead after placement in the epidural space. The active anchor kit is provided with two active anchors and a torque wrench to tighten the anchor.

1.4.7   Evoke Intraoperative Cable Kit

Ref No. 3034

The Evoke Intraoperative Cable allows the surgeon to connect the eCLS to the implanted leads for intra-operative testing.

1.4.8   Evoke Patient Controller (EPC)

Ref No. 3040

The Evoke Patient Controller (EPC) allows the patient to control their therapy and actively monitors the stimulator battery status and other elements of the system. The EPC and the stimulator communicate with each other wirelessly.

1.4.9   Evoke Charger

Ref No. 3006

The Evoke Charger allows the patient to recharge the battery in a CLS. The Charger coil (attached to the Charger) is placed over the CLS and charge is transferred to the CLS through thin clothing and the skin. The Charger kit also includes a power adapter for recharging the Charger.

1.4.10 Evoke Accessory Belt

Ref No. 3039

The Evoke Accessory Belt is an elastic belt with a pouch to hold an eCLS or Charger coil.

1.4.11 Evoke Clinical Interface (CI)

Ref No. 3024

The Evoke Clinical Interface (CI) is a tablet computer with a preinstalled programming application (the Clarity Programming Application, CPA) used by the clinician to adjust the therapy settings of the Evoke CLS and eCLS.

1.4.12 Evoke Clinical System Transceiver (CST)

Ref No. 3004

The Evoke Clinical System Transceiver (CST) is a plug-in device (USB connection) that enables exchange of information wirelessly between the CI and the stimulator.

2. Indication for use

The Saluda Medical Evoke SCS System is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

2.1 Contraindications

The Evoke SCS System should not be used in patients who:

- Do not receive effective pain relief during trial stimulation.
- Are unable to operate the Evoke SCS System.
- Are unsuitable surgical candidates.

3. Safety Information

For general system warnings and precautions refer to the Evoke SCS System Surgical Guide, accessible at http://www.saludamedical.com/manuals.

The Evoke CI is a tablet computer. For non-therapy specific warnings and precautions on this product refer to the device manual accompanying the CI tablet.

3.1 Precautions

3.1.1   Unsupported software applications

⚠️Do not load additional software applications onto the Evoke CI. The Evoke CI has all the necessary software required to interact with and program the Evoke SCS System from Saluda Medical. Other applications could interfere in unpredictable ways with the programming software installed and affect the delivery of therapy for patients. Any required software installations shall be supported directly by Saluda Medical representatives or via detailed instructions concerning specific installations as required.

3.1.2   Unsupported hardware

⚠️Do not connect any device to the Evoke CI other than the supplied: keyboard, power adapter and Evoke CST. Do not connect the Evoke CST to any device other than a Saluda Medical supplied Evoke CI. Unsupported hardware could interfere in unpredictable ways with the programming software installed and affect the delivery of therapy for patients. Do not modify, tamper, or use other equipment with the Evoke SCS System.

For data file extraction, it is permissible to use an external USB memory stick that has passed a screening check by an up-to-date anti-virus software application, but no files should be transferred onto the CI unless otherwise instructed by Saluda Medical to do so.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

3.1.3   Shared IT networks

⚠️Network connection (via Wi-Fi) is only permitted to secure networks. Connecting to unsecure networks could lead to the modification of the CI system or software that interfere in unpredictable ways with the programming software installed and affect the delivery of therapy for patients.

3.1.4   Modification of the programming software

⚠️Do not attempt to modify the Clinical Programming Application (CPA) software which comes preinstalled on the CI for the programming of Saluda Medical neurostimulators. Any deletion or

modification of files associated with the CPA could adversely affect the system's ability to effectively adjust therapy for patients.

Required software upgrades will be supported directly by Saluda Medical representatives or via detailed instructions concerning specific upgrades as required. Additionally, any stimulator software upgrades will be fully supported by Saluda Medical representatives – do not attempt to modify the stimulator software without Saluda Medical's instruction.

3.1.5   Non-sterile components

⚠️**DO NOT STERILIZE** the CI, CST, eCLS, EPC or Charger; these items are not to be sterilized and doing so could irrevocably damage the devices.

3.1.6   Clinical staff training

⚠️Clinical staff using the CI/CST to program the Evoke SCS System must be adequately trained in the programming of SCS systems generally. Additionally, clinical staff programming the Evoke SCS System should have been trained based on the instructions within this manual. A poor understanding of the programming of SCS systems generally, and the Evoke system specifically, could cause unpleasant or painful stimuli for patients.

3.1.7   Electromagnetic interference (EMI)

⚠️As the CI communicates via the CST to the neurostimulator (eCLS or CLS) wirelessly, the quality of this connection can be adversely affected by some types of electrical equipment that generate EMI. Such equipment should be avoided where possible when programming and/or suspected if communication between stimulator and CI/CST is poor. Examples of such equipment found in clinical environments include but are not limited to: Mobile phones, electro-surgery tools, electromagnets, radiofrequency identification devices and emergency vehicle/services radios. Avoid use of the CI and CST adjacent to or stacked with other equipment, because it could result in improper operation. If such use is necessary, observe the CI, CST and the other equipment to verify that they are operating normally. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm to any part of the Evoke System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

3.1.8   General precautions for the CI and CST

⚠️The CI is a critical piece of equipment to enable the delivery of therapy. Always handle it with care and regularly inspect the device for damage and/or impaired functioning. Never modify the CI in any way. If you have concerns about the integrity of the CI/CST, contact Saluda Medical representatives to arrange repair or replacement. The CI runs on a rechargeable battery and can be used wirelessly or while plugged in via the power adapter supplied. Care should be taken to keep the CI well charged so it can be used in clinical environments where plug sockets are not

readily available. Always have a spare charged CI available in case of malfunction. Do not use the CST at the patient's home.

4. Introduction

4.1 Evoke Clinical Interface (CI)

The CI is a tablet computer. For full specifications and instructions for use of the tablet computer refer to the device manual accompanying the CI tablet. The computer is not physically modified in any way. The CI operates on the Microsoft Windows platform. The CI is supplied with the software necessary for programming Saluda Medical stimulators pre-installed, and no other software should be installed on the device.

Upon starting and logging in to the CI, the user will immediately find a program icon . This will lead the user into the Clinical Programming Application (CPA) that enables programming of either the Evoke eCLS or CLS.

> **Note**: Login password for the CI will be provided by Saluda Medical representatives and cannot be changed. All potential CI operators should be made aware of this password.

4.2 Evoke Clinical System Transceiver (CST)

The CST is a radio telemetry device that enables communication between the CI and the stimulator (eCLS or CLS). Commands generated through the CPA loaded on the CI are sent to the stimulator and data is received back from the stimulator to display in the CPA via the CST. The CST is connected to the CI via a USB connector and receives power from the CI via this link.

5. Clinical Interface (CI) setup

This section describes how to setup the CI and connect to a stimulator.

5.1 Connecting the CI to the CST

To program and download data from the eCLS or CLS, communication must first be established. The CST connects to the CI to communicate using a radio signal transmitted to the eCLS or CLS.

1. Turn on the CI and login to the 'Saluda' account.
2. Check that the time and date on the CI are correct (bottom right corner of CI screen). Refer to CI instructions to change the time and date.
3. Connect the CST to the CI with the USB connection.
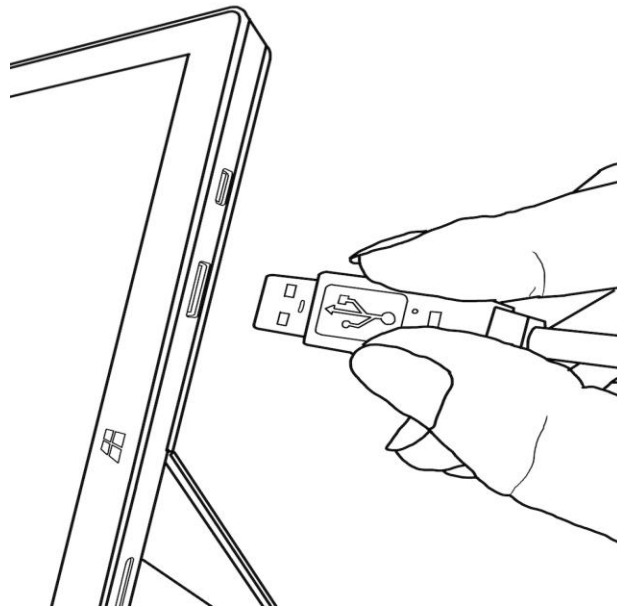
Figure 5.1: Connecting the CST to the CI USB port.

4. Position the CST near the stimulator.

    Note: The CST can link with the stimulator within a 1.0 m (3.3 ft) radius.

    Note: Electromagnetic interference can affect the quality of this wireless link; see Section 3.1.7 - Electromagnetic interference (EMI).

5.2 Starting the CPA and connecting the CI to eCLS/CLS

1. Touch the Evoke Clarity Clinical Programing Application (CPA) icon 🅢 on the CI start menu (or double-tap the icon on the desktop) to start the CPA.
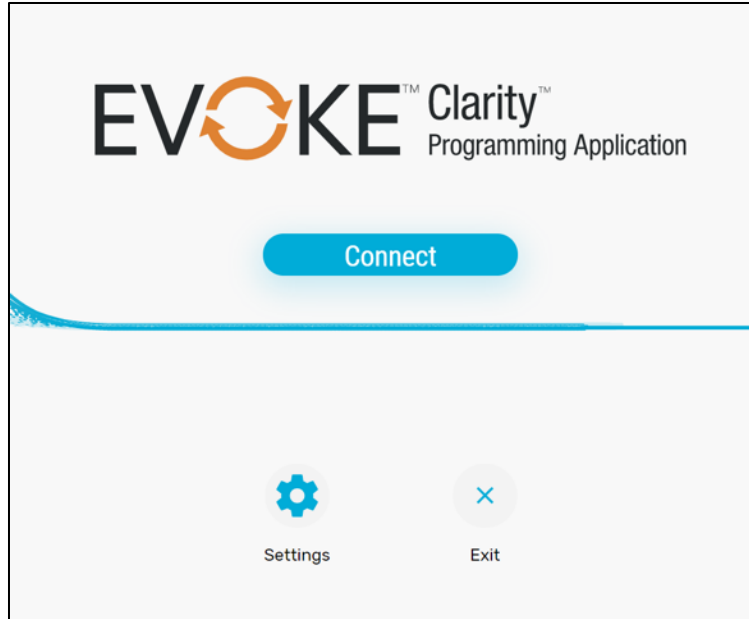
Figure 5.2: Start Screen.

2. Touch *Connect* on the start screen to access the Connect screen (as shown above). A scan for nearby stimulators will begin automatically, and a list of stimulators within range will appear on this screen (example shown in Figure 5.3).
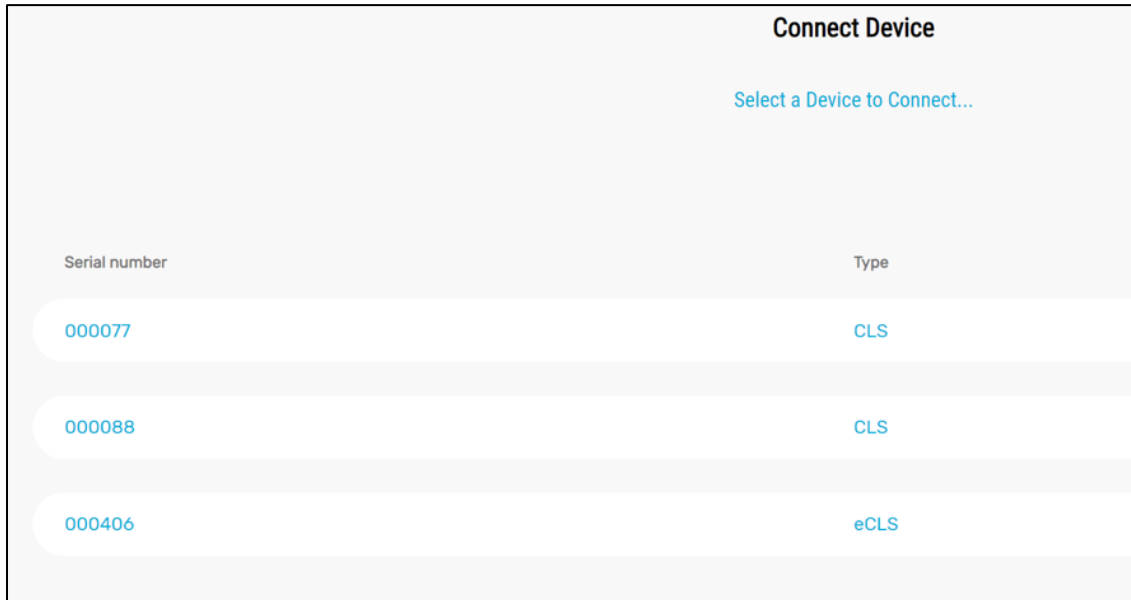
Figure 5.3: Connect screen showing the result of a scan for nearby stimulators.

3. Select the device you wish to connect to, based on serial number and type (see Figure 5.3).
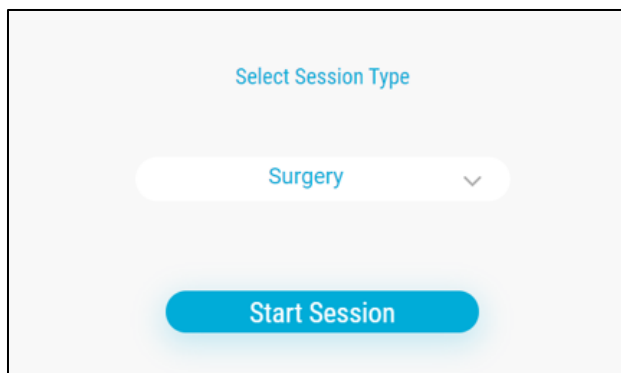
Figure 5.4: Select Session Type.

4. The CPA will connect to the stimulator and retrieve some stimulator data (such as patient ID, battery level, and programs).

⚠ **Caution**: Before connecting the CPA to the stimulator, ensure that you have a magnet and paired EPC available at all times during the programming session in case they are needed to stop stimulation (refer to the Evoke SCS System User Manual).

5. Select Session Type from the dropdown menu and touch the Start Session button to start your programming session (see Figure 5.4). The programming session will begin on the home page (see Section 6.2).

6. Using the Clarity Programming Application (CPA)

This section describes the layout of the Clarity Programming Application (CPA) and how to use it to setup a new patient profile and complete a programming session.

6.1 CPA Main Screen Layout

The components of the CPA Main screen are displayed throughout the programing session and are shown below in Figure 6.1.
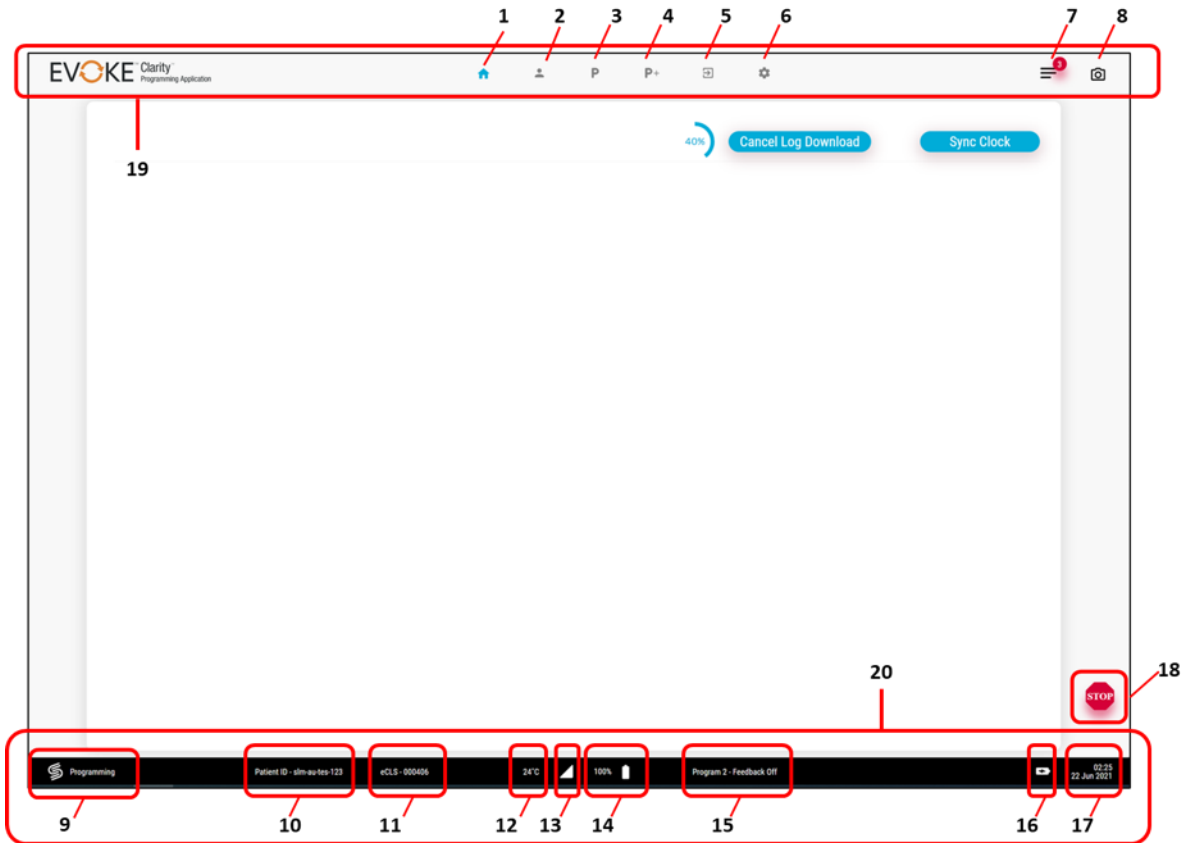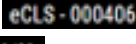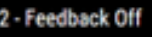
Figure 6.1: Static outer CPA screen layout.

1. Home page
2. Patient page
3. Programming page
4. Neurophysiological Measurements page
5. Disconnect page
6. Settings page
7. Notes pop-up
8. Screenshot button
9. Session type
10. Patient ID

11. Stimulator Serial Number
12. Stimulator Temperature
13. Telemetry Strength
14. Stimulator Battery
15. Program Number and Feedback Status
16. CI Battery
17. CI Time and Date
18. Stop Therapy
19. Header
20. Status Bar

6.1.1   Header and Status Bars

The header and status bars will be present at all times after you have connected to a device and started a session. Likewise for the *Stop* button.

The header bar contains:

1. The menu bar for accessing different pages,
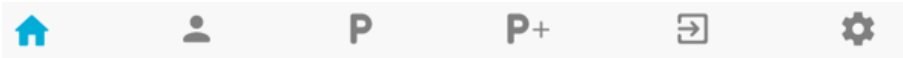
2. Notes button (for bringing up the Notes pop-up window).

   Note: There is an area to the left of the Notes button where you may see a black banner with a message that appears for 5 seconds; see Section 6.1.2 for additional information about notifications.

3. A button for taking screenshots.

The status bar (footer) contains:

1. Information about the session, i.e. session type (on the left)
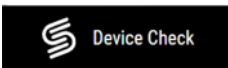
2. Information about the connected device, such as patient ID, serial number, temperature, communication quality indicator, battery level, and current program.

3. Information about the CI (on the right), such as battery level, time, and date.

6.1.2   Display of Notifications

Events and alerts are displayed in the CPA using various notification types depending on the immediate significance to the user (described in more detail in the following pages). The different notification types, in order of importance, are:

1. **Pop-up:** Alerts that require immediate attention and possible action from the user or events regarding important functions that completing successfully.

2. **Banner:** Common events and alerts (this is the most frequent form of notification).

3. **Button icon:** Alerts regarding an issue with a specific feature/button.

In some cases, alerts may result in multiple notification types (See example in Figure 6.2).
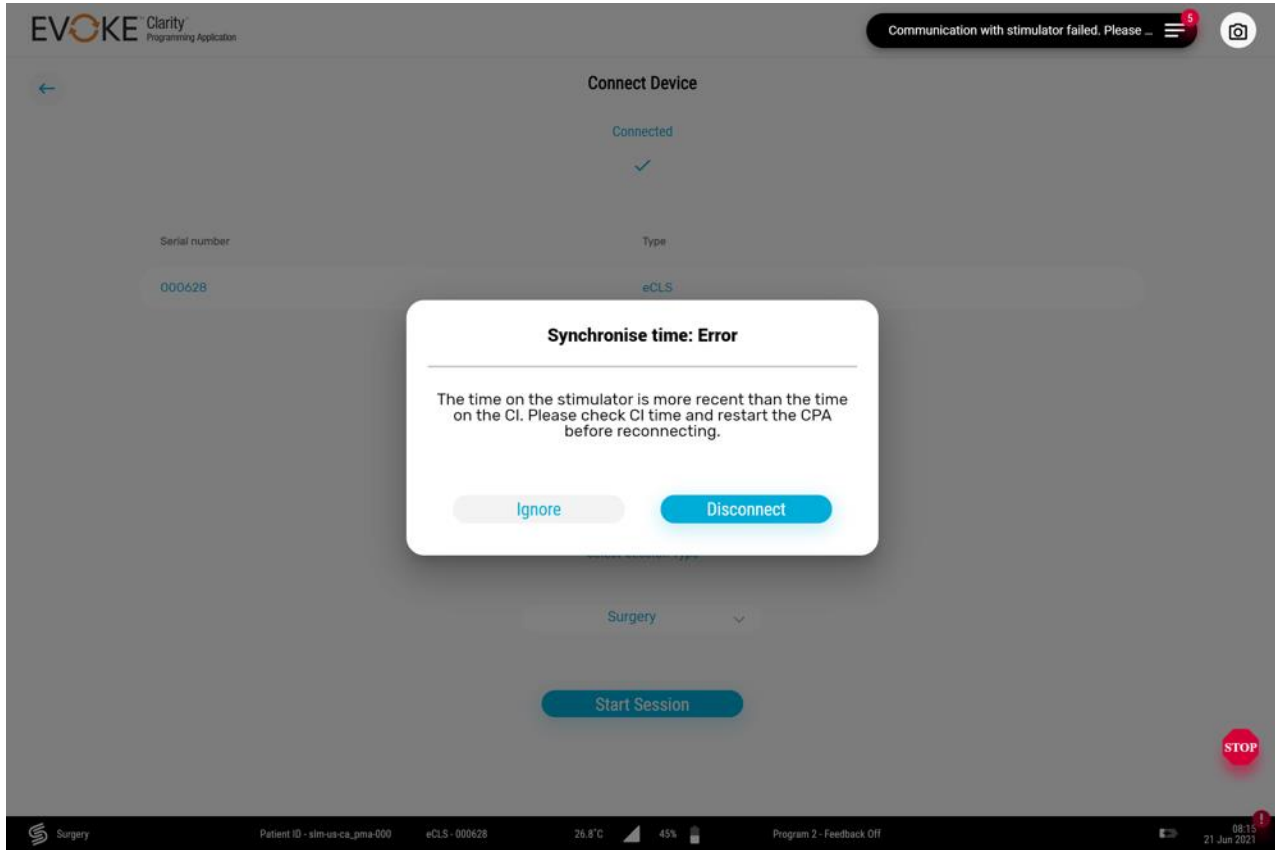
Figure 6.2: Example of an alert generating both a banner and a pop-up.

Alerts and events are also viewable in the *Notes* window (see Section 6.2.4). When either of these occur, the number above the *Notes* icon will be incremented to let the user know there is new

information . Clicking on the *Notes* button will scroll to the most recent note and reset the counter (Figure 6.3).
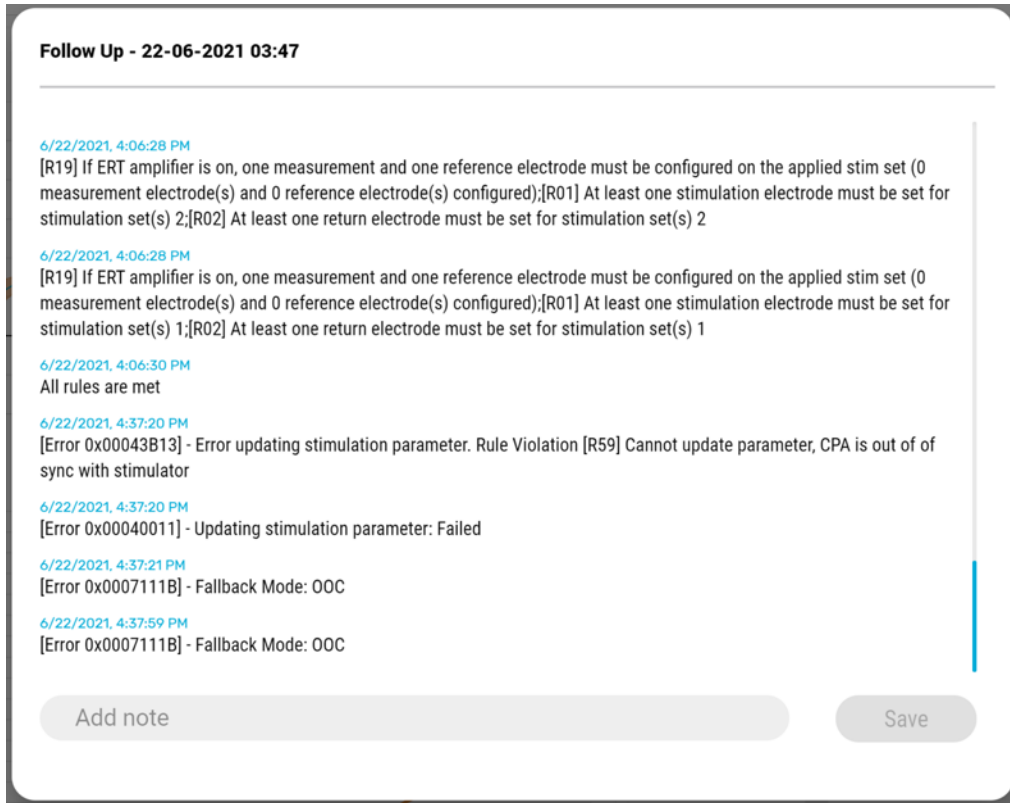
Figure 6.3: Multiple events and alerts displayed in the *Notes* window.

For more information regarding how the stimulator responds to certain alerts see Section 8.

6.1.2.1   *Pop-ups*

Pop-up alerts notify the user of an event that requires immediate attention. They may require an action from the user or simply an acknowledgement before proceeding further (Figure 6.4).

Note: The *Stop* button is always available, even when a pop-up is obscuring the screen.
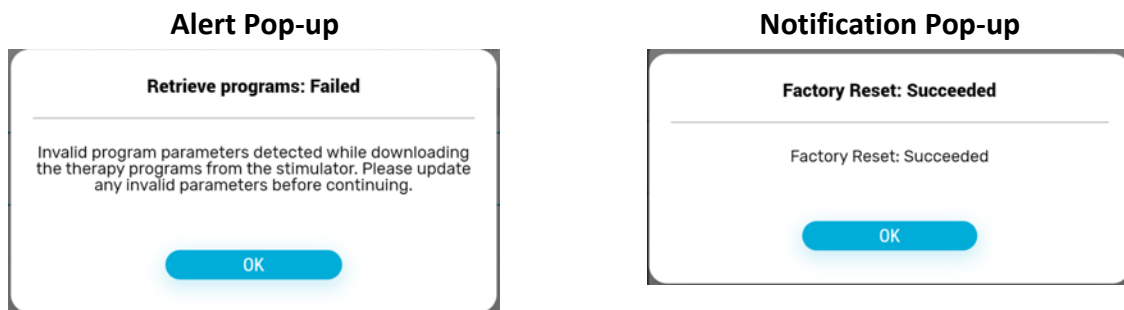
Figure 6.4: Example of pop-up alerts and notifications.

6.1.2.2 *Banners*

Banners are the most common form of notification, letting the user know a certain alert has been triggered. In some cases, they also indicate what needs to be done, or that a task has completed successfully (Figure 6.5).

Banner Alert   **Banner Notification**

Figure 6.5: Example of banner alerts and notifications.

6.1.2.3 *Button icons*

Certain alerts will trigger an *alert* icon ❗ to appear over a button to let the user know there is an issue with or relating to that feature. Clicking on the *alert* icon will result in additional information being displayed about the issue(s). See example in Figure 6.6.
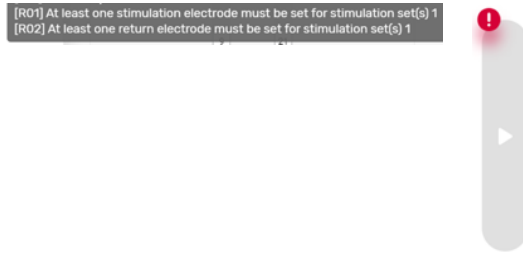
Figure 6.6: Example of an *alert* icon over a button and the information displayed when the icon is clicked.

If a parameter has been updated in the CPA, but not yet sent to the stimulator, a 'sync' icon will appear over the unsync'd parameter and the associated program number to let the user know the CPA and stimulator are not synchronized (Figure 6.7).
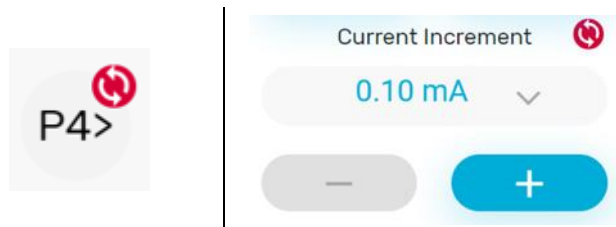
Figure 6.7: *Left:* One or more parameters of a program has not been sent to the stimulator. *Right:* The current increment for the selected program has not been sent to the stimulator.

6.1.2.4 *Safe Mode errors*

A Safe Mode error will be indicated with an initial pop-up and a persistent banner notification that will remain until the issue has been resolved (Figure 6.8). Safe Mode errors must be cleared

before stimulation can continue. A Safe Mode error is also indicated with the *Contact Clinician* indicator ⟩ on the patient's EPC and Charger (see Evoke SCS System User Manual).

If a Safe Mode error is encountered:

1. Save the programs on the stimulator (if you want to keep them and they have not already been saved).

2. Perform a 'Soft Reset' using the CPA to take the stimulator out of Safe Mode (see Section 6.7 for where to find the *Soft Reset* button).

   Note: The pop-up that is trigged by a Safe Mode error enables the user to perform a 'Soft Reset' without going to the *Settings* screen.

3. Report the occurrence of the Safe Mode error and accompanying code to Saluda Medical.
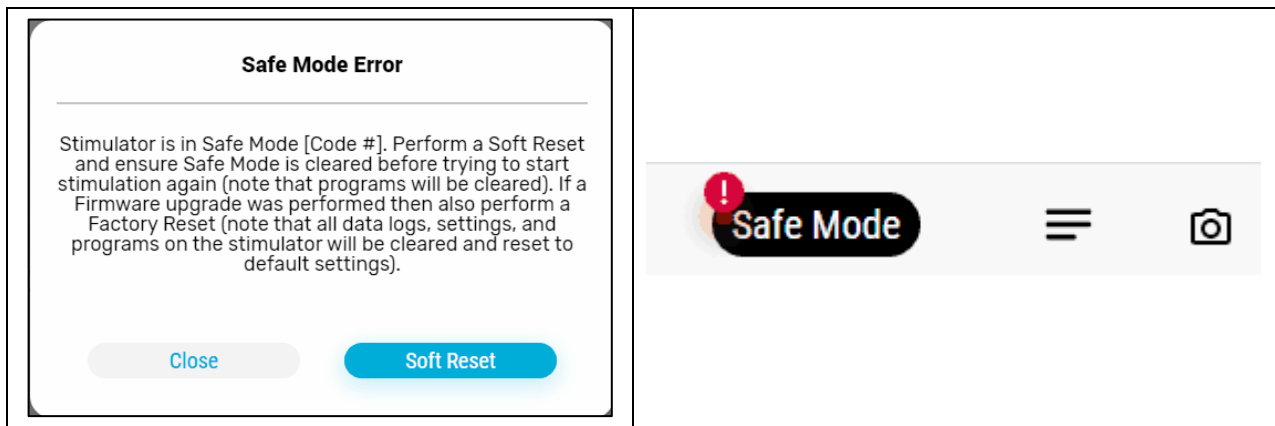
Figure 6.8: *Left*: Pop-up indication that the stimulator is in *Safe Mode* ('#' will be the error number) and the subsequent steps required. *Right:* The persistent banner notification will be displayed until the stimulator is no longer in *Safe Mode*.

6.1.2.5 *Communication Quality Indicator*

The quality of the radio communication between the CST and the stimulator is indicated on the status bar, see examples in Figure 6.9.
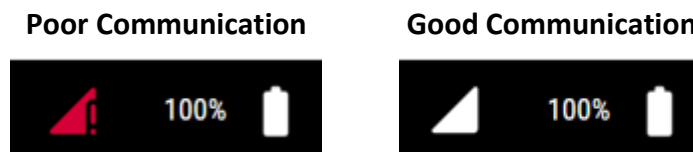
Figure 6.9: States of the communication quality indicator, shown adjacent to the stimulator battery level.

If there are any notifications regarding poor communication (e.g., a banner or the communication quality indicator), do not make any further changes to the program until communication is restored. If there are frequent failed commands and/or extended time between the response to commands, move the CST closer to the stimulator to improve communication. If issues persist,

stop stimulation (see Section 6.4.4.1) until communication with the stimulator is re-established. If unresolved, restart the CPA or the CI.
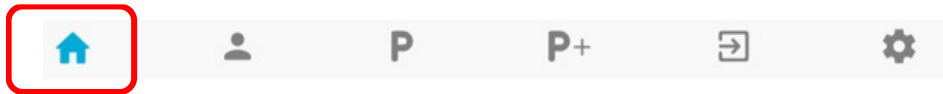
6.2 Home Page

The home page is the first page you see after connecting to a device and starting a session. This is where logs are downloaded from the stimulator, and the clock of the stimulator is synchronized with the CI clock.

6.2.1 Download logs

If stimulation is off, then logs will automatically download upon entry to this page. You will see a progress indicator showing how much time remains to complete the download.

Note: Depending on the amount of data saved on the device this could take several minutes. Downloading can be cancelled but this is not recommended as any system error and device usage logs will be missed.

If logs don't download automatically, then touch the STOP button to stop stimulation, and then touch the button.

The CPA will display *Logs Successfully downloaded* in the header when it has successfully connected and downloaded all of the logs from the stimulator (see Figure 6.10 for an example of this banner notification).

Note: If any logs cannot be downloaded, an error message will be displayed in the Notes.
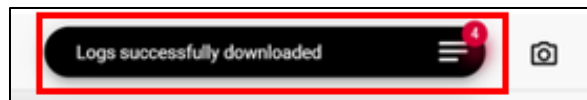
Figure 6.10: Logs Successfully downloaded.

Log is maintained when the system is powered down and contents are unaffected after the device has experienced a total loss of power.

6.2.2 Set stimulator time

The stimulator time is normally synchronized automatically to the CI time during connection and data download (except when stimulation is on during connection).

1. Check that the time and date on the CI are correct (bottom right corner of CPA screen, Figure 6.1) Refer to the CI instructions (see Section 5) to change the time and date, and reconnect to the stimulator after correcting the date/time on the CI.

2. Touch the *Sync Clock* Button to set the stimulator time to the CI time (if the time is not

already synchronized).

6.2.3 Check stimulator battery status

The stimulator battery status is displayed in the status bar (see examples in Figure 6.11 and Figure 6.12). If the battery voltage is low (≤28% full) the battery icon will be red. Refer to the Evoke SCS System User Manual for instructions on charging the CLS battery or to the Evoke SCS System Surgical Guide for charging the eCLS battery.

Figure 6.11: Stimulator battery status**.**

Figure 6.12: Stimulator battery status – battery is low voltage.

6.2.4 Notes

During a programming session the data may be annotated with a time-stamped note.

A number will appear next to the Notes button to indicate how many notes, notifications, or alerts have been added since the last time you opened the Notes pop-up window .

1. Open the Notes pop-up window.
2. Type a text note in the *Add note* field.
3. Touch the *Save* button to save the text note with a time-stamp in the clinical data log file.
4. A screenshot of the CPA programming screen is also saved in a 'Screenshot' folder for this visit, and can be easily retrieved from within the Notes pop-up window.

6.2.4.1 *Other system generated notes*

In addition to manually entered notes, the system also records a note (and saves a screenshot) in the following situations:

1. When the activation plot level markers (T, C-, C+, M) are activated (from the P page)
2. When Start AP and Stop AP buttons are touched on the F tab (from the P page).
3. When a posture is selected and deselected in the E tab (from the P page).
4. When Neurophysiological Measurement workflows start and end (from the P+ page).

6.2.5 Screenshots

In addition to the automatically generated notes and screenshots mentioned above, screenshots may be saved manually.

1. Touch the screenshot button to save a screenshot of the CPA programming screen.
2. A number next to the Notes button will increment to reflect the addition of this note to

the list of screenshots .

3. The screenshot is saved in a 'Screenshot' folder for this visit and can be easily retrieved from within the Notes pop-up window.
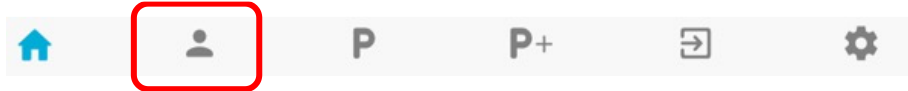
6.3 Patient Page

Within the Patient page there are two main tabs:

1. Patient Profile Tab .

2. Patient Survey Tab .

The Patient Profile should be completed before the stimulator is programmed for the first time. Patient Surveys may be available to document more information about the session, patient demographics, and pain history. They are also used to generate the RECAP Visit report.

6.3.1 Patient Profile for a new patient

1. Touch the Patient Profile Tab .
2. Check the appropriate 'Consent' setting (yes/no) provided by the patient.
3. Complete the profile information to automatically generate a Patient ID.
4. Complete the Patient ID by adding the patient's 3-digit number to the end of the ID. This will also be displayed in the status bar.

Figure 6.13: Example of a completed Patient ID.

6.3.2 Retrieve Patient Profile for an existing patient

1. Patient Profile information is retrieved from the stimulator on connection and displayed on the *Patient Profile* page (see Figure 6.13).

2. Ensure the correct 'Consent' setting is selected and adjust if it has changed since the previous visit.

3. Check that all fields in the Patient Profile have been retrieved and are correct.

6.3.3 Patient Survey

A survey may be completed to document the patient's demographics, pain history, and experience with SCS.

1. Touch the Patient Survey Tab 💬 .

2. The Surveys list displays all the surveys that have been created on the device (see example in Figure 6.14). The first survey created will always be the 'Baseline' survey. Any subsequent surveys will be 'Follow Up'.

Figure 6.14: Survey list.

1. Create a new survey
2. View/Edit survey

3. If more than 2 surveys have been created and saved to the device, the CPA will only automatically download the baseline survey and most recent follow-up survey.

6.3.3.1 *Baseline Patient Survey Data*

The Baseline Patient Survey is used to document information about the patient and their pain, prior to SCS. This survey information will be used to populate the follow-up surveys in order to compare how the patient is doing throughout their experience with SCS.

1. Touch Create
2. A new baseline survey will open

Within the survey, there are five pages, as shown in Figure 6.15.
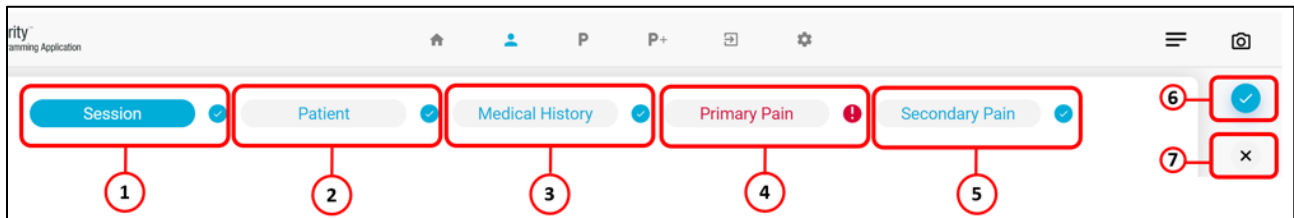
Figure 6.15: Survey Page Layout.

1. Session page   5. Secondary Pain page
2. Patient page   6. Save Survey button
3. Medical History page   7. Close Survey button
4. Primary Pain page

The colored page header (i.e. 'Session' in the above example) is the survey page currently being displayed. If there is a checkmark ✓ next to the page header, the page is either fully completed or complete enough to be saved. If there is a alert icon ❗ next to the page header (and the font is red), the page is incomplete and needs to be filled out before saving the survey. Information listed in the table below in **bold** are only available in Baseline surveys.

Table 6.1: Baseline Survey Information Collected.

Page Name	Key information collected
Session	Visit Reason, Physician Information, Patient Goals
Patient	Demographics and CLS Activation Date
Medical History	**Previous Neuromodulation Treatments** and Medications
Primary Pain	**History of pain**, Pain Drawing and Scores, QOL
Secondary Pain	Pain Drawing and Scores

6.3.3.2 *Shading Body Areas*

1. Eraser Tool
2. Paint Brush Tool
3. Clear All Tool
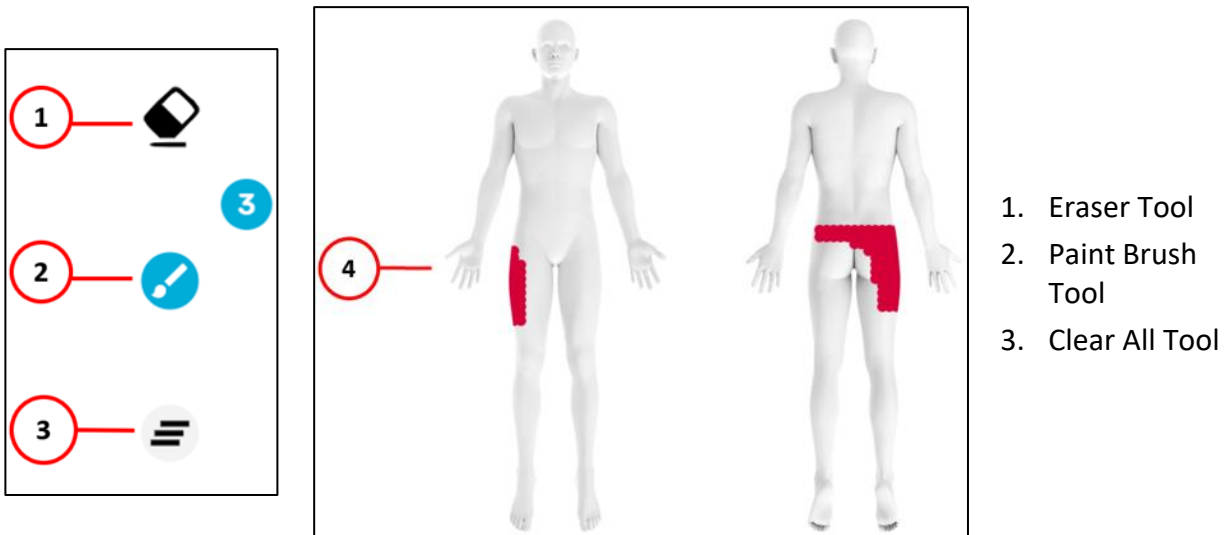
Figure 6.16: Legend for shading body areas.

1. The Eraser and Paintbrush Tool have 3 resolutions options: 1, 2, 3. Both default to ③, to be used for broader strokes, while ① is to be used for finer strokes.

2. If you want to clear the entire drawing, select the 'Clear All' button. A pop up will confirm if you want to clear shading.
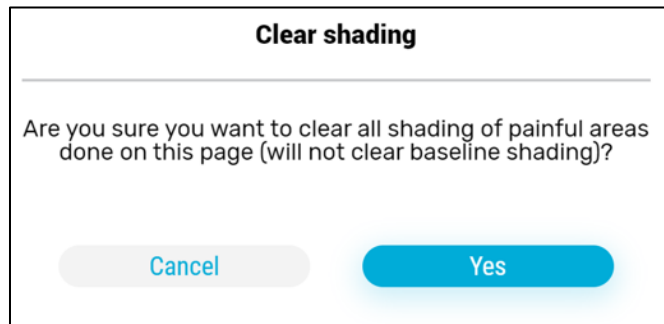
Figure 6.17: Clear shading.

6.3.3.3 *Save the Survey*

Touch the ✓ to save the Survey to the stimulator (Figure 6.15).

6.3.3.4 *Close the Survey*

If you need to exit the survey prior to completing and saving, there are two options.

1. Option 1: Touch the ✕ . This will bring up a pop-up message confirming that you want to close the survey without saving.

- Touch 'Yes' to confirm.

2. Option 2: Touch any of the component tabs at the top of the screen (i.e. [P]). This will bring you to the selected page (i.e. the program page).

- When you return to the Survey [icon] screen, instead of saying 'Create' at the top of the screen, it will now say 'Resume'.

Surveys	View or edit any Survey stored on the device. Don't forget to complete this session survey			Resume
Type		Date	Time	View/Edit
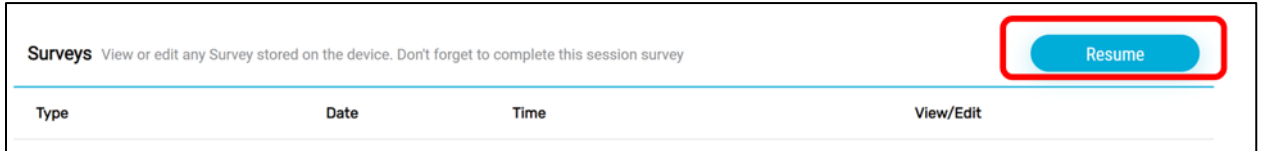
Figure 6.18: Survey Screen after closing a survey without saving.

- To continue editing the survey, touch 'Resume'. A Resume Survey pop-up window will appear, asking if you want to resume or create a new survey. Touch 'Resume' to continue editing the survey. Touch 'New Survey' to discard the survey you exited.

6.3.3.5 *Follow-up Patient Survey*

Data is pulled into the Follow-up Survey either from the baseline survey or the latest Follow-up survey, whichever is more recent. Information listed in the table below in **bold** are only available in Follow-up surveys. Some of this data is used in the RECAP Visit Report-Session Outcomes.

Table 6.2: Follow-Up Survey Information Collected.

Page Description	Key information collected
Session	Visit Reason, Physician information, Patient Goals, **Preferred Program**
Patient	Demographics, CLS Activation Date, **Satisfaction**
Medical History	Previous Neuromodulation Treatments and Medications
Pain	Pain Drawing and Scores & QOL
Sensation	Stimulation Sensation Information

6.4 Programming Page

The Programming page is where you set and adjust stimulation for the stimulator. Within the Programming page there are several tabs on the left-hand side that go through a typical programming session workflow. Along the bottom of the Programming page, there are several Thumbnails that can be selected to personalize and configure which Displays you'd like to see on the screen at any given time.
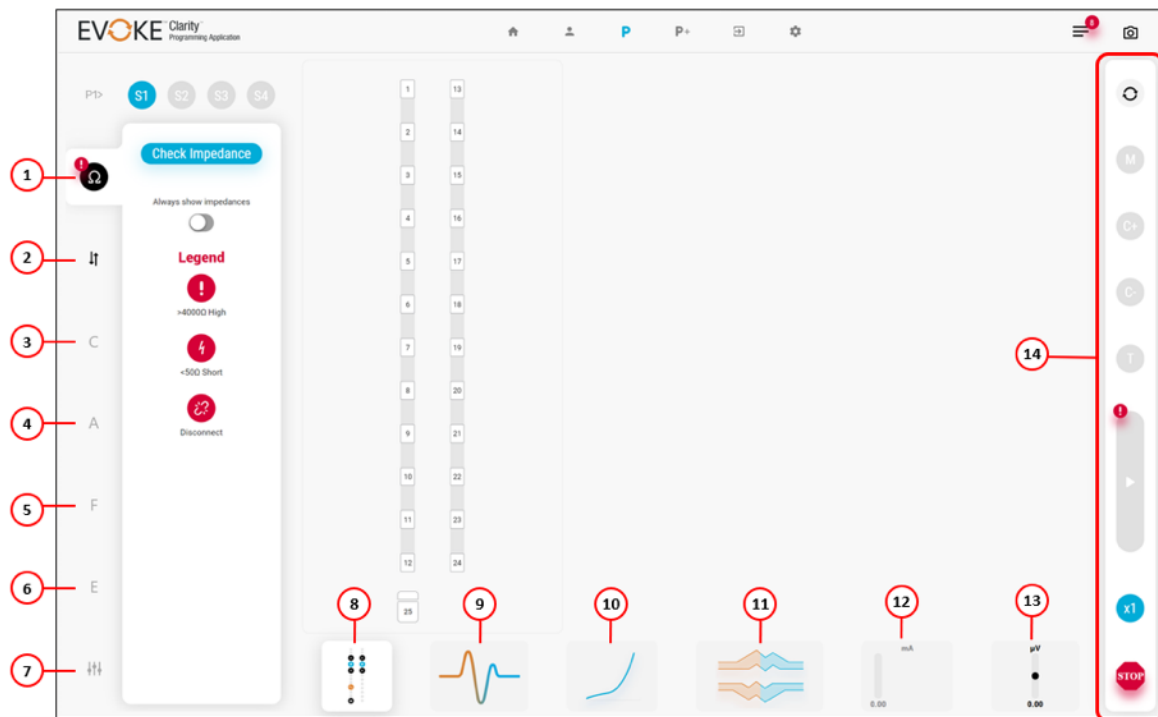
Figure 6.19: Programming Page Layout.

1. Impedance tab
2. Lead Orientation tab
3. Coverage tab
4. Acquisition tab
5. Filter tab
6. Evaluation tab
7. Program Settings tab
8. Electrode display thumbnail
9. ECAP display thumbnail
10. Activation Plot display thumbnail
11. Rolling Plot display thumbnail
12. Current (mA) display thumbnail
13. ECAP amplitude (µV) display thumbnail
14. Right control panel

For every programming session:

1. Use the Impedance tab to measure the electrode impedances to determine if all connections are intact (see section 6.4.1).

2. Use the Lead Orientation tab to set up or confirm lead orientation (which lead is on which

side, and relative offset) (see section 6.4.2).

3. Follow the Coverage, Acquisition, Filter, and Evaluation tabs (CAFE) to complete a programming session

4. Add/remove displays from the main part of the screen, at any time, using the corresponding thumbnails.

A typical programming session consists of the following steps. Refer to the subsequent sub-sections for more information on the pages and tabs used for each step.

Coverage (see Section 6.4.4)

1. Test stimulation on several electrodes and ask the patient to report where they feel paresthesia.

2. Determine the stimulation electrodes and parameters that give the best paresthesia coverage of the patient's painful dermatomal area(s).

Acquisition of ECAP (see Section 6.4.5)

3. Determine the settings that provide a good measurement of the neural response (ECAP) to stimulation.

Fitting the Filter (see Section 6.4.6)

4. Determine the filter and sensitivity settings for optimum closed-loop stimulation.

Evaluation of Settings (see Section 6.4.7)

5. Assess the performance of closed-loop stimulation with different postures.

6. Review and adjust the final program settings for the program (see Section 6.4.8).

7. Save the program to the eCLS/CLS memory and proceed to set up a maximum of four programs.

6.4.1 Impedance Tab

Measure the electrode impedances to determine if all connections are intact between leads, any lead adapters, and the stimulator.

1. Touch **P** in the header to get to the Programming page.

2. Touch the Impedance Ω tab, and the Check Impedance button (see Figure 6.20).

3. The impedances on the 24 electrodes and CLS case (E25) will be shown in the electrode display (see example in Figure 6.20).

4. Optional: To keep impedances displayed on every tab, touch the **Always show impedances** toggle to enable.
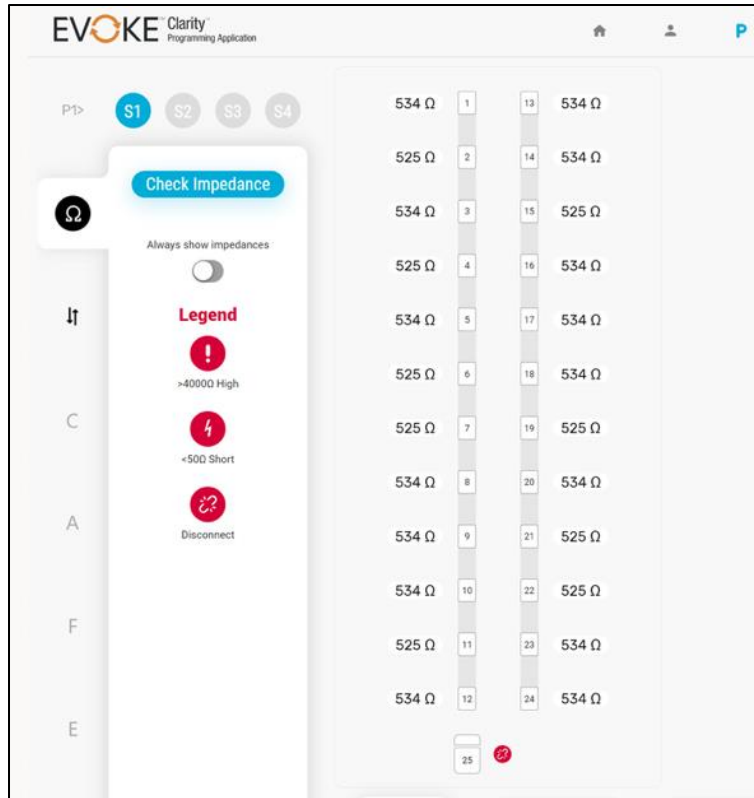
Figure 6.20: Impedances displayed on the 24 electrodes and CLS case (E25).

5. An electrode with an exclamation mark ⚠ has high impedance (> 4000 Ω) and might be disconnected. A disconnected electrode shows 🔗 and cannot be used for stimulation. Measurement electrodes that are disconnected will not record valid ECAPs.

    Note: The CLS case cannot be used for stimulation and may show as high impedance (> 4000 Ω). The CLS case may be used for recording even if high impedance is shown.

6. Electrodes with a lightning bolt ⚡ may be shorted (< 50 Ω) and care should be taken when programming.

    ⚠ **Caution:** If the electrodes show as disconnected:

    - Wipe any blood or fluid off the lead connection contacts.
    - If the system is fully implanted, a high impedance may indicate that the lead is broken or dislodged from the header and the patient may require revision surgery if stimulation cannot be adequately reprogrammed.

    Note: When connected to an eCLS the CLS case is disconnected and cannot be used.

6.4.2 Lead Orientation Tab

1. Touch the **Lead Orientation** tab (see Figure 6.21).
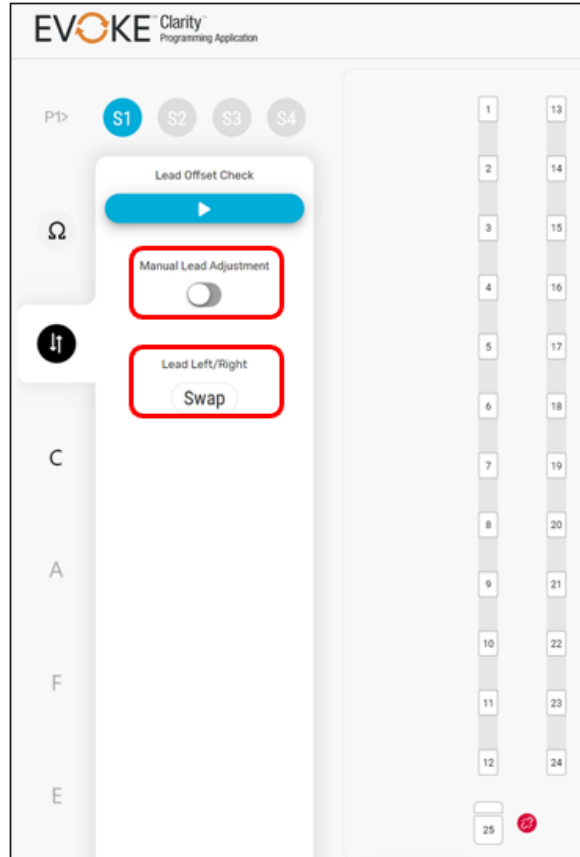
Figure 6.21: Set up Lead Orientation.

2. Touch the **Manual Lead Adjustment** toggle to enable your ability to move a lead on the screen.

3. Select and drag either lead to move it up or down.

4. Select the **Lead Left/Right Swap** button to switch sides to a position that reflects the lead location. This will aid in determining the best stimulation and measurement electrode combination.

5. **Optional:** Run the **Lead Offset Check** to estimate the vertical alignment of the implanted leads (see Section 6.4.2.1).

   Note: You can touch and drag the leads up/down on any tab to adjust the view. The orientation will remain fixed.

6.4.2.1 *Lead offset check*

Collect data to estimate the vertical alignment of the implanted leads. The lead offset check will report the peak artefact measured at different electrode locations.

To estimate the lead offset:

1. Touch the **Lead Orientation** tab .

2. Touch *Start* to start the artefact measurement.

Note: During the test, stimulation will be turned on at 0.5 mA with 200 μs pulse width, which is typically not felt by the patient.

If necessary, touch the *Stop* button **STOP** to stop the stimulation at any time and cancel the lead offset check.

3. Wait for the measurements to complete. The test will cycle through up to 6 stimulation locations, until sufficient data is collected.

   Note: You may stop the lead offset check at anytime by touching the *Cancel* button

   . The results for stimulation locations with completed measurements will be plotted, but the measurements may be invalid.

4. After completion, the results of all peak artefact measurements will be plotted (Figure 6.22).
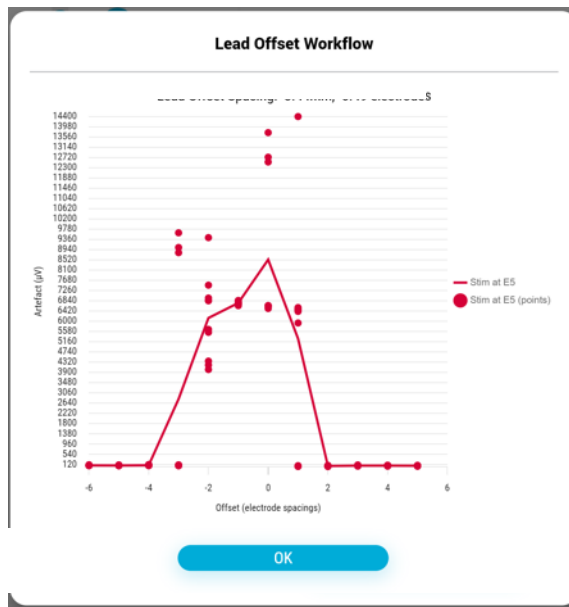
Figure 6.22 Artefact plot. The peak of the plot indicates the lead offset (electrode spacings).

   Note: Negative lead offset values indicate that lead 1 (E1-E12) lies proximal to lead 2 (E13-E24). Positive values indicate that lead 1 lies distal to lead 2.

5. Click 'Ok' to close the pop-up. The original program and Stim-Set(s) parameters will be restored.

   Note: The original program still needs to be sent to the stimulator after it has been restored.

6. Refer to Section 6.4.2 if you want to adjust the lead orientation.

6.4.3   Program management Tab

The program management tab is where you change, add, delete, save, or load a Program or Stim-Set. It appears at the top of the left panel, but is normally accessed while you're in the C, A, F, or E tab. The stimulator can hold up to four different programs, each with up to four Stim-Sets (see section 6.4.4.2 for information on using Stim-Sets). Each program on the CPA is represented by a number in the Program Management tab. Any program that is run on the stimulator (with stimulation turned on) is automatically saved to the stimulator. When a program displayed on the CPA differs from what's on the stimulator, a sync icon will appear next to that number.
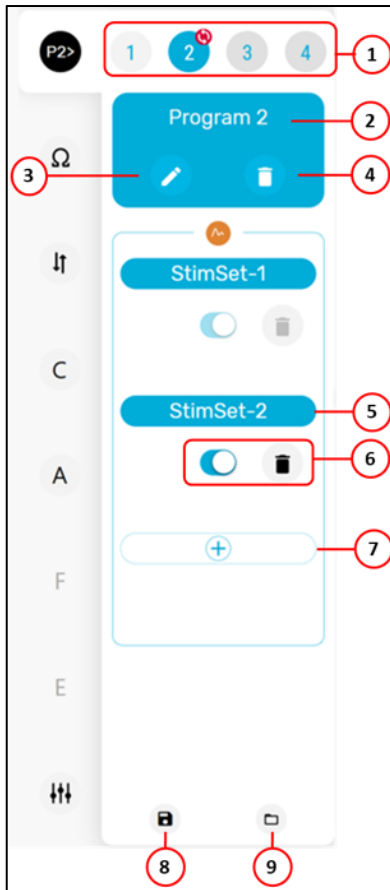
1. Program Select buttons

2. Program Label

3. Edit button (for Paresthesia Map)

4. Delete Program button

5. Stim-Set Label

6. Stim-Set Toggle and Delete buttons

7. Add Stim-Set button

8. Save Programs button

9. Load Programs from File button

Figure 6.23 Program Management tab layout.

6.4.3.1   *Select the Program to view/run/configure:*

1. Turn stimulation off before making any program configuration changes.
2. Touch the Program Number on the left panel (e.g. P1>). This will bring up the Program Management tab.
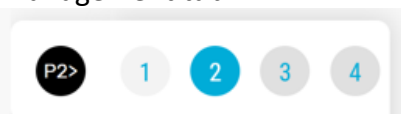
- White font on a colored (blue or orange) background represents the currently selected Program (e.g. P2 in the example above).

- Colored font on a grey background represents a Program that's not currently selected (e.g. P1 in the example above).
- Dark grey background represents a Program that is empty (e.g. P3 and P4 in the example above) and has not been enabled.
- An enabled program may still be empty if it has been selected but not configured.
- If color is blue, this means that the currently selected program has closed-loop disabled. If color is orange, this means that the currently selected program has closed-loop enabled. This color will be reflected throughout the screen elements.
- If any program on the CPA has not been run on the stimulator (such as a new program, or one that has been modified), a red sync icon will appear next to the number of the unsynchronized program.
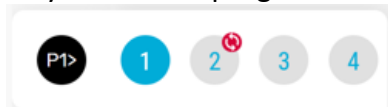
- If you navigate away from the Program Management tab, a red sync icon will appear next to the Program Number (e.g. P1>).
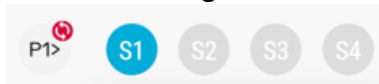
- Once a program has been run, it will be saved to the stimulator and the sync icons will go away.

3. Touch the number of the program to run/view/configure.

6.4.3.2 *Delete/clear a Program:*

1. Touch the number of the program you want to delete/clear.

2. Touch the trash icon under the Program label.

6.4.3.3 *Record paresthesia information for a Program:*

1. Touch the edit icon under the Program label.
2. A window with a body map will pop-up (see Figure 6.24).

   Note: The shading information will also be saved within the SaveFile, if you save a program.

Figure 6.24: Body Map window.
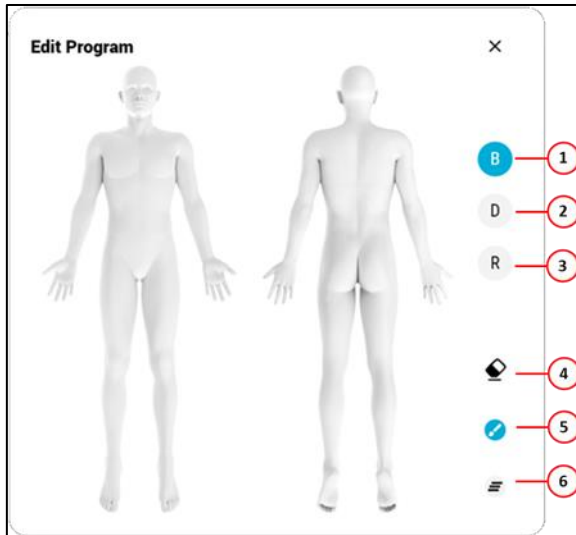
1. Blank body map view
2. Dermatome map view
3. Anatomical Regions map view
4. Eraser tool
5. Paint brush tool
6. Erase all button

3. Select **B** to display a blank body map (Figure 6.24).

4. Use the touchscreen or touch pad to draw on the body map to mark the areas of paresthesia coverage associated with the selected program.

5. Touch the Eraser Tool to change your cursor from a paint brush to an eraser, if needed.

6. Touch the 'Erase all' button to erase all marks made on the current view, if needed.

7. Select **D** to change the display to dermatome map view. Entire dermatomes will be highlighted for any that contain marks made on the body map.

8. Select **R** to change the display to anatomical regions view. Entire regions will be highlighted for any that contain marks made on the body map (see example to the right).

9. Markups made in these body maps will be saved with the associated program on the CPA.
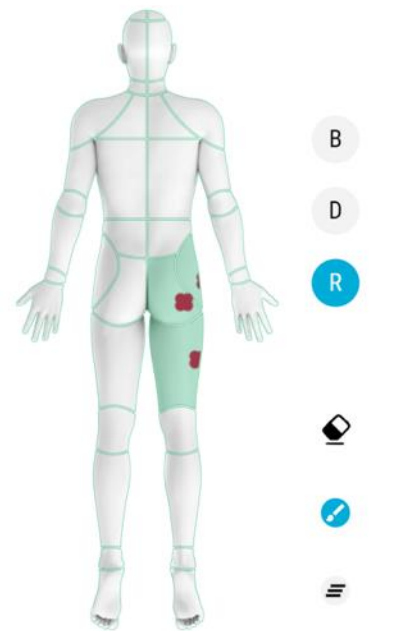
6.4.3.4 *Save Programs*

Programs are saved in two places:

1. … Into a SaveSlot in the CPA.

   There are 5 available SaveSlots. Upon connection to a stimulator, programs are loaded from the stimulator and automatically saved into SaveSlot #1 (the top-most row). A SaveSlot holds information from all 4 programs, as displayed on the CPA at the time they were saved. You can also save programs manually at any time during a programming visit.

They will go into the next available (blank) SaveSlot. If there are no blank SaveSlots, they will overwrite the oldest SaveSlot.
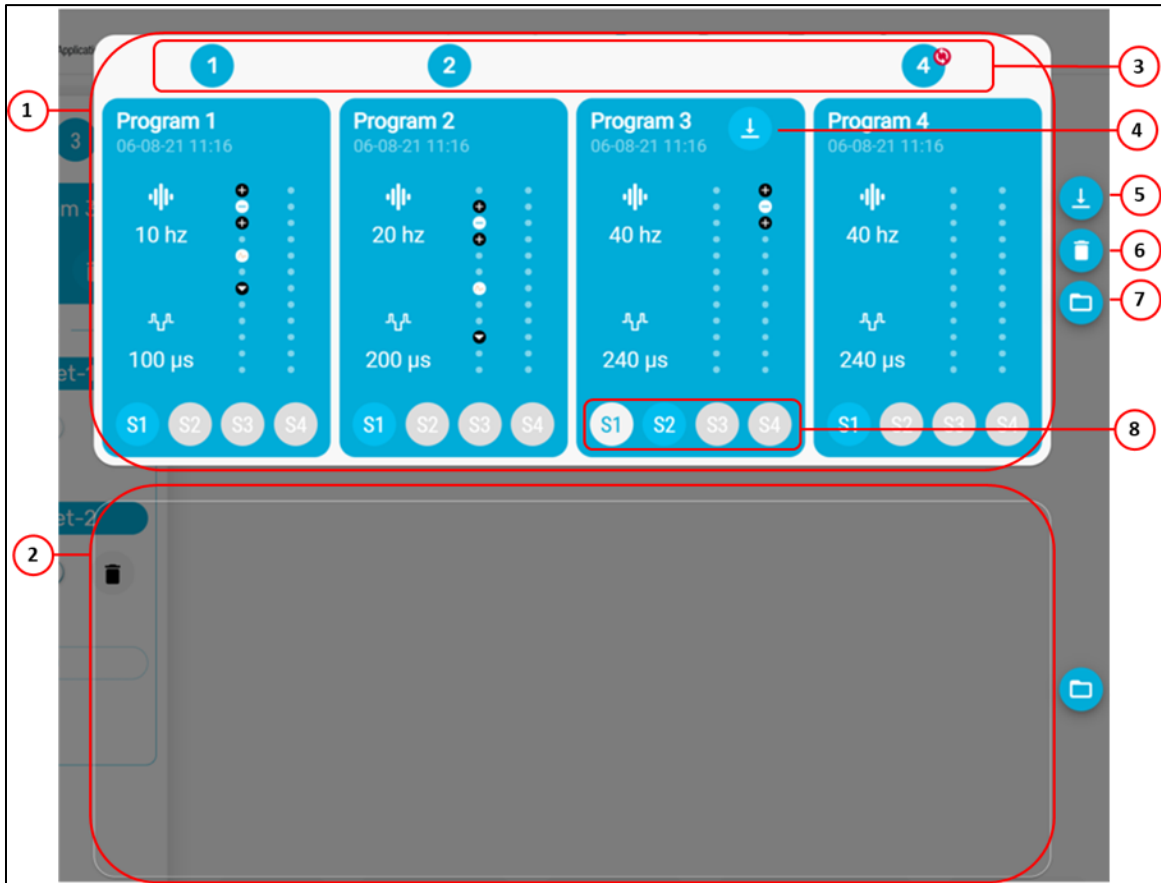
Figure 6.25: Layout of the SaveSlot window.

1. SaveSlot #1
2. SaveSlot #2 (scroll down to see the other 3 SaveSlots)
3. Indicators of Synchronization
4. Load Program/Stim-Set button
5. Load (all) Programs button
6. Delete SaveSlot button
7. Load SaveFile button
8. Stim-Set selector

When viewing the SaveSlots, numbers above each program (Indicators of Synchronization) indicate programs on the CPA that match what's saved in the SaveSlot. If the program on the CPA does not match exactly the program that's on the stimulator, then a sync icon will also appear (for example, see Program 4 in Figure 6.25).

2. … Into a file in the SaveFile folder for the visit.

Programs are saved automatically into a SaveFile after connection and upon disconnection, and any time you save programs manually.

SaveFiles are stored in the SaludaData folder for this session (see Section 6.7.1.1).

To save programs:

1. Access the Program Management tab.

2. Touch the Save Programs button .
This will save the entire set of programs into the next available SaveSlot and into a SaveFile.

6.4.3.5 *Load a Program/Programs from memory*

From within the Program Management tab, with stimulation off, you can load previously saved programs into your programming session from a SaveSlot, or from a SaveFile (via a SaveSlot).

From SaveSlots (within the CPA):

1. Touch the Program label to access the SaveSlots menu (Figure 6.25).
2. a. Select the group of programs you want to download, and touch the adjacent 'Load (all)

   Programs' button . This will overwrite all 4 programs displayed on the CPA.
   or

   b. Select the specific program you want to download from within a SaveSlot, and touch

   the 'Download Program' button that appears in that program box. This will only overwrite the program that you selected when you opened the SaveSlot menu.

From SaveFiles:

If you have programs saved on the CI that are not in a SaveSlot (i.e. from a previous day's

programming session), you will find these via the 'Load Programs from File' button .

There are two ways to load programs from a SaveFile into a SaveSlot:

1. From within the Program Management tab…

   a. Touch the 'Load Programs from File' button .
   b. Navigate (through the file manager window that pops up) to the file to be loaded.
   c. Click 'Open'. This will load a previously saved program into the next available SaveSlot.

2. From within the SaveSlot menu…
   a. After touching the Program label (to open the SaveSlot menu)
   b. Scroll to the SaveSlot (row) that you want to load the SaveFile into (i.e. an empty one, or one that you want to over-write)

   c. Touch the 'Load Programs from File' button next to the selected SaveSlot.

6.4.3.6 *Add a Stim-Set*

From within the Program Management tab (Figure 6.23),

1. Select the Program number to edit.

2. Touch the 'Add Stim-Set' button.

6.4.3.7   *Remove a Stim-Set*

1. You can delete a Stim-Set by touching the Delete button 🗑 within the corresponding Stim-Set box. You cannot delete Stim-Set-1.

2. You can disable/enable a Stim-Set with the toggle ◖ in the corresponding Stim-Set box. You cannot disable Stim-Set-1.

6.4.3.8   *Change which Stim-Set is used for measurement*

Stim-Set-1 is the Stim-Set that contains measurement electrodes. To change which Stim-Set to use for ECAP measurements:

1. Access the Program Management tab.

2. Touch and hold the label for the Stim-Set that you want to use.

3. Drag it to the top (until it's over Stim-Set-1) and release.

6.4.3.9   *Select the Stim-Set to view and/or configure:*

From within any other tab (outside of the program management tab), select a Stim-Set number (S1, S2, S3, or S4). These appear in place of the program numbers that appear when you're in the program management tab.
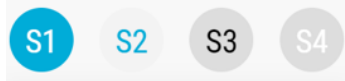
- White font on a colored (blue or orange) background represents the currently selected Stim-Set (e.g. S1 in the example above).

- Colored font on a light grey background represents an enabled Stim-Set that's not currently selected (e.g. S2 in the example above).

- Black font on a darker grey background represents a Stim-Set that has been enabled and then disabled, and it will be re-enabled if you select it (e.g. S3 in the example above).

- White font on a darker grey background represents a Stim-Set that is empty, and cannot be selected (e.g. S4 in the example above).

6.4.3.10 *Load a Stim-Set from memory*

You can load a single Stim-Set from a SaveSlot into any Stim-Set of a Program.

1. Touch the Stim-Set label for the Stim-Set to be over-written. This will take you to the SaveSlots menu.

2. Select the specific program you want to download a Stim-Set from.

3. Select the specific Stim-Set within the selected program that you want to download.

   - When it has been selected, the Stim-Set Selector will have a colored background

with white font (e.g. S2 in the example below).

- An empty Stim-Set will have a grey background (e.g. S3 and S4 in the example below).
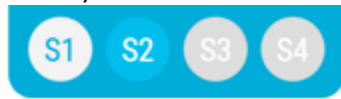
4. Touch the 'Download Stim-Set' button that appears in that program box. This will overwrite the Stim-Set that you selected when you opened the SaveSlot menu.

6.4.4 Coverage Tab

a. Touch the **Coverage** tab on the left column navigation. It is recommended that the **Electrode**, **ECAP**, and **Current (mA)** displays are selected to view on the CPA screen.
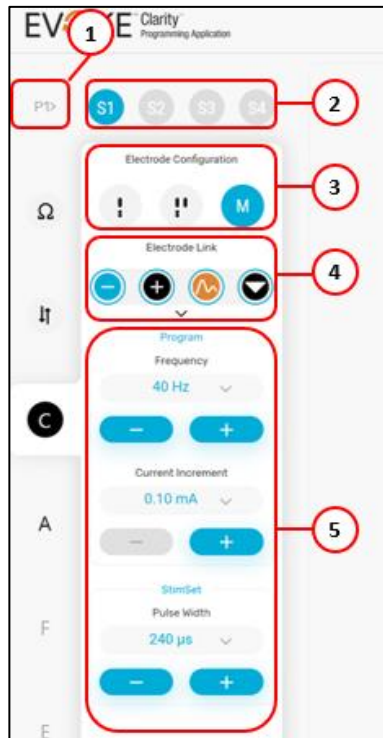
1. Program Number
2. Stim-Set Number
3. Electrode Configuration
4. Electrode Link
5. Program and Stim-Set parameters

Figure 6.26: Coverage Tab Layout.

b. Stop stimulation if Stimulation is running.

c. Note the Program Number and Stim-Set number that's currently selected next to the Program management tab (i.e. P1> S1 in the above figure).

d. Choose how you would like to select the stimulation electrodes using the options under Electrode Configuration.

Figure 6.27: Electrode Configuration options.
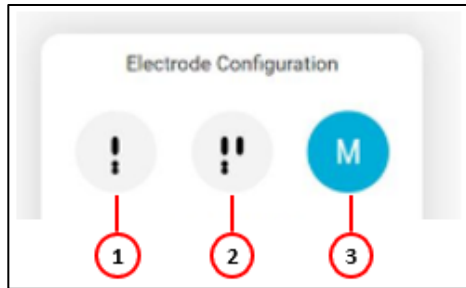
1. Automatic Single Lead
2. Automatic Dual Lead
3. Manual

3. For **Automatic Single Lead** electrode configuration, touch the electrode you want to use as the cathode in the Electrode display. Touch on the cathode again to cycle through electrode configurations. The CPA will automatically select the recording and reference electrodes for you.

Tripolar: Single lead	Bipolar: Single lead
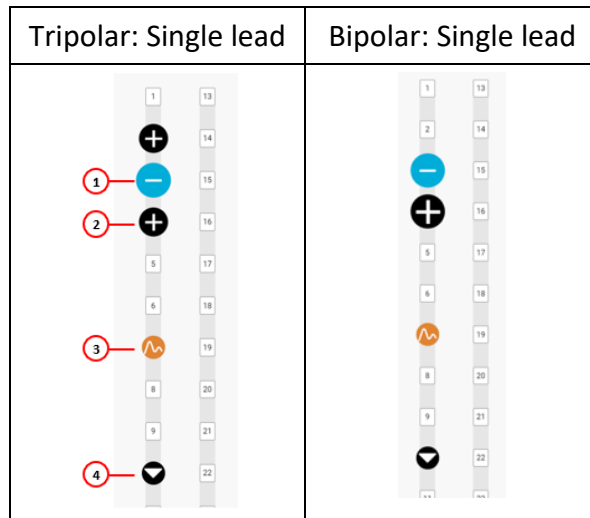
Figure 6.28: Automatic Single Lead.

1. Cathode (Stimulating electrode)
2. Anode (Return electrode)
3. Recording electrode
4. Reference electrode

4. For **Automatic Dual Lead** electrode configuration, touch the electrode you want to use as the cathode in the Electrode display. Touch on the cathode again to cycle through configurations. The CPA will automatically select the recording and reference electrodes for you.

Tripolar: Dual lead	Bipolar: Dual Lead
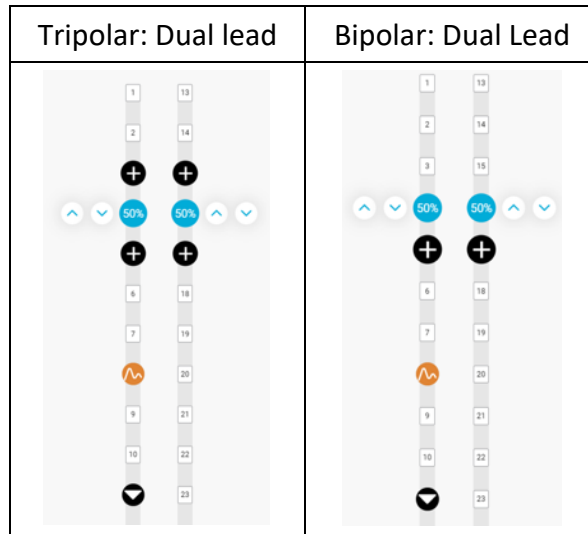
Figure 6.29: Automatic Dual Lead.

5. Current steering is available whenever there is more than one cathode, to balance the strength of paresthesia felt in different areas of the patient's body.

- The cathodes will now be displayed with a % value and ^ v icons.

- The % value represents the % of the total current going to that cathode.

- To deliver more current to a cathode touch the ^ icon. To deliver less current to a cathode touch the v icon. The % of current delivered at the other cathodes will automatically adjust to keep the total at 100%.

6. For **Manual** electrode configuration, you can manually change, add, or remove electrodes by selecting the electrode you wish to change, then choosing if you want to remove it, or change it to a cathode, anode, recording, or reference electrode.

To move selected electrodes, there are three options that can be used for Manual electrode configuration (Figure 6.30):
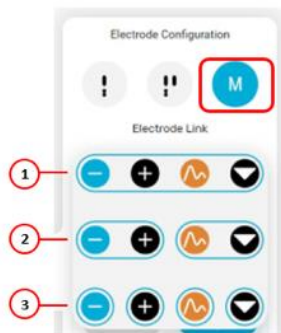
1. Link all
2. Link only stimulation and link only Measurement
3. Independent electrode selection

Figure 6.30: Electrode Link.

- **Link all** – Moves cathode, anode, recording, and reference electrodes together. When you select and drag one of them to a new electrode location in the Electrode display.

- **Link only Stimulation and link only Measurement electrodes**
    a. Moves cathodes and anodes together when you select and drag either a cathode

or anode to a new electrode location on the Electrode display.

    b. Moves recording and reference electrodes together when you select and drag either a recording electrode or reference electrode to a new electrode location on the Electrode display.

- **Independent electrode selection** – Allows you to move anode, cathode, recording, and reference electrodes individually to any new electrode location on the Electrode display.

7. All settings are set to default values for new programs. You can adjust the individual stimulation parameters in order to adjust paresthesia coverage (e.g. Pulse Width) and/or different sensation (e.g. Stimulation Frequency) by touching on "Advanced" within the **Program and Stim-Set Parameters** in the **Coverage** tab (see Figure 6.31).

- To set standard stimulation parameters when reprogramming existing programs, go to the **Program Settings** tab → *Advanced* → touch the *Reset* button under "*Reset Program to Defaults*."

8. Restart stimulation with the new stimulation configuration.

    Note: You cannot change the cathode or anode electrodes while stimulation is running.
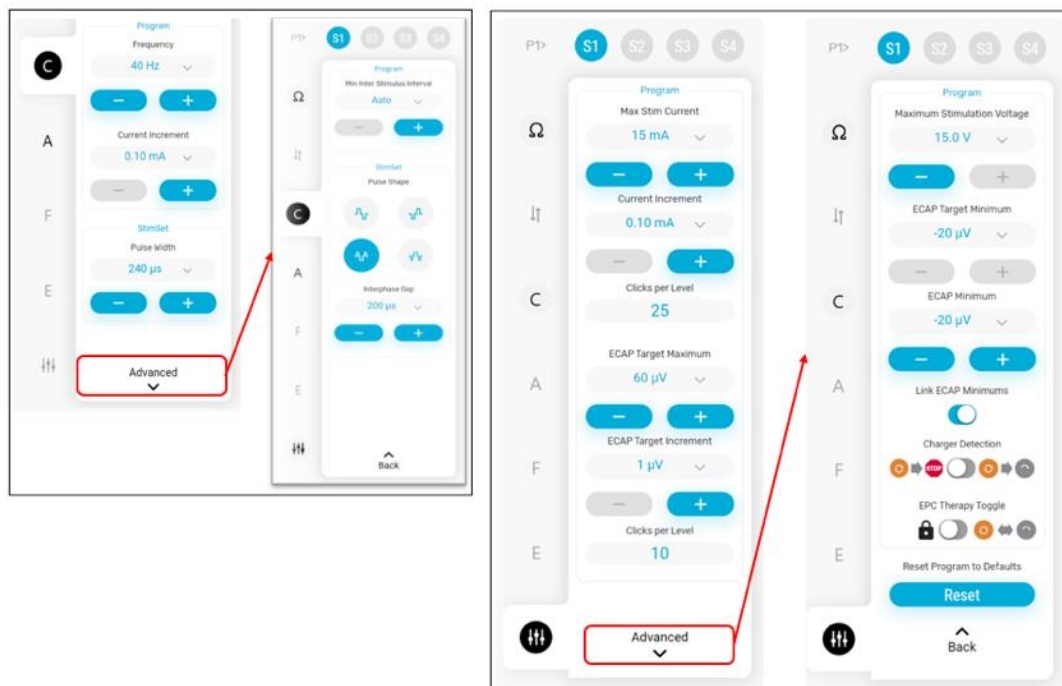
Figure 6.31: Default values for new programs within **Program and Stim-Set Parameters** in the **Coverage** tab (Left) and the **Program Settings** tab (Right).

6.4.4.1 *Start and stop stimulation*

1. Touch on the Start Stimulation button (see Figure 6.32) on the right control panel of the **Programming** page to start stimulation.
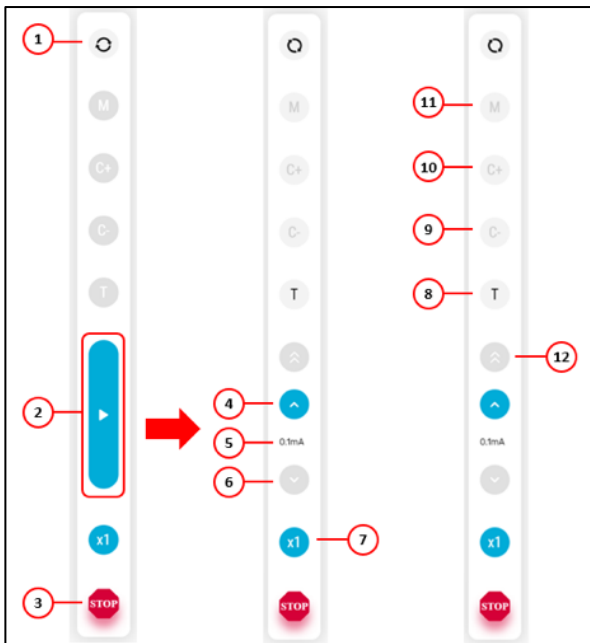
1. Enable or Disable Closed-Loop stimulation
2. Start stimulation
3. Stop stimulation
4. Increase current
5. Current increment
6. Decrease current
7. Multiply current increment
8. Threshold
9. Comfort Minus
10. Comfort Plus
11. Maximum
12. Ramp up

Figure 6.32: Right Control Panel on the Programming page, with Start Stimulation button and stimulation controls. With Closed-loop disabled, buttons on the screen will turn **blue** to indicate they are active.

Note: The ECAP and Current (mA) thumbnails will become active, e.g. they will update continuously with the ECAP amplitude and current setpoint. When Closed-loop is enabled, they will show the ECAP target and the stimulation current respectively.

2. Touch the *Increase current* button ⌃ to increase stimulation current to the desired level (mA).

3. Touch the *Decrease current* button ⌄ to decrease stimulation current.

4. Touch the *Stop* button 🛑 to stop stimulation at any time.

    Note: The current will increase/decrease by the current increment (mA) set in **Program and Stim-Set Parameters**. Touch the **Multiply current increment** button x1 to increase the current increment by up to 2x. The current scale is shown in the **Current (mA)** display. The scale will extend to the maximum current set in the **Program and Stim-Set Parameters** tab (see Figure 6.33).

Figure 6.33: Current (mA) display (top) and thumbnail (bottom).
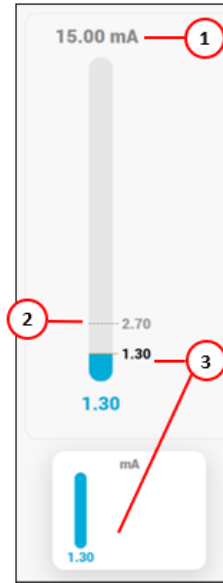
1. Max Stim Current setting

2. Previous current level (when stimulation was last stopped)

3. Current set point (mA) (desired level)

4. Active Current level (mA) (which lags set point)

6.4.4.2 *Interleaved stimulation*

A program may contain several interleaved stimulation sets (Stim-Sets), targeting several areas of pain. The CPA has the ability to concurrently run up to four (4) Stim-Sets per program. Refer to Section 6.4.3 Program management Tab for details on how to setup, configure, and change Stim-Sets.

The first Stim-Set (S1) is the one with which measurements are made. It is the only one that can contain measurement electrodes.
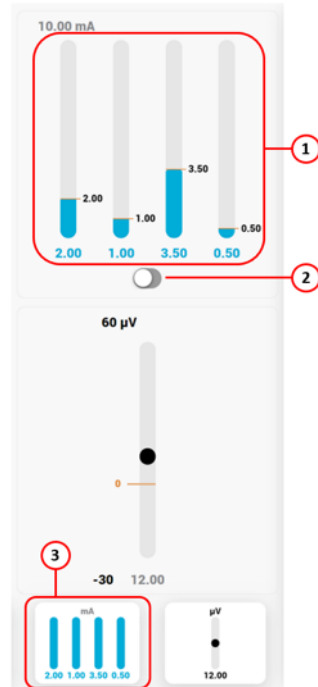
1. Current bars in the current display—one for each Stim-Set that is enabled.

2. Stim-Set Group toggle

3. Current thumbnail—with set point levels for each Stim-Set

Figure 6.34: UI elements related to Interleaved Stimulation.

Note: Enable the Stim-Set Group toggle to group the Stim-Sets so that current changes for all Stim-Sets concurrently.

- If disabled (to the left), then only the Stim-Set that is currently selected will change.

- If enabled (to the right), Stim-Sets are grouped. This is the default.

Set up interleaved stimulation

To set up multiple Stim-Sets in a program:

1. Start with the first Stim-Set (SS1). When you first setup a program, you are working with S1.

2. Create a second Stim-Set (e.g. S2), or as many Stim-Sets as you need, via the Program management tab (see Section 6.4.3).

3. Ungroup the Stim-Sets.

4. For each Stim-Set:

    a. Select the Stim-Set number at the top of the left panel.

    b. Configure the stimulation settings in the C tab (see Section 6.4.4 Coverage Tab).
    Note: Frequency, maximum current, and current increment are equal across stimulation sets, while pulse width may be set independently.

    c. Note the threshold level.

5. After configuring each Stim-Set, set their relative levels.

    a. Select the Stim-Set number at the top of the left panel.

    b. Increase current to the threshold level noted above.

6. After setting each Stim-Set current to their respective threshold levels, group the Stim-Sets using the Stim-Set Group toggle.

7. Increase current (with Stim-Sets grouped now) to the desired level.

8. Measurement is only enabled for the first stimulation set (S1). The ECAP measurement and closed-loop settings from the first stimulation set are used for closed-loop control of all stimulation sets.
   To change which electrode configuration is associated with the measurements, see Section 6.4.3.8.

9. Complete the ECAP acquisition, filter fitting, and evaluation steps as you would for a program with no interleaving.

   Note: Closed-loop stimulation will only operate based on the settings in the first Stim-Set. The closed-loop control will vary the current to each Stim-Set such that the ratio of current between Stim-Sets remains constant.

Enable/Disable a stimulation set in a program

To enable/disable a Stim-Set in a program: See 6.4.3.9 in Program Management tab.

Things to be aware of when enabling/disabling a Stim-Set:

- When a Stim-Set is disabled, the Stim-Sets that are still enabled will continue to increase/decrease at the previous ratio.

- If a stimulation set is disabled its ratio will be set to 0 and it will need to be reconfigured.

Changing the ratio between Stim-Sets

The ratio between Stim-Sets can be changed, even during stimulation.

1. Ungroup the Stim-Sets (using the Stim-Set Group toggle).

2. Select a Stim-Set number to be adjusted and change the current to the new desired level.

3. Re-group the Stim-Sets (using the Stim-Set Group toggle) and continue stimulation as normal.

6.4.5 Acquisition Tab

Touch the **Acquisition** tab to start setting up an optimal ECAP measurement. It is recommended that the **Electrode** and **ECAP** displays are selected to view on the CPA screen (see Figure 6.35).

The stimulator records the ECAP signal and displays a plot of the ECAP on the **ECAP** display. ECAP measurement is only possible for stimulation frequencies of 200 Hz or less (250 Hz or less for Amplitude option). ECAPs can only be generated and measured above a minimum (threshold) current, which varies with different postures and between patients.
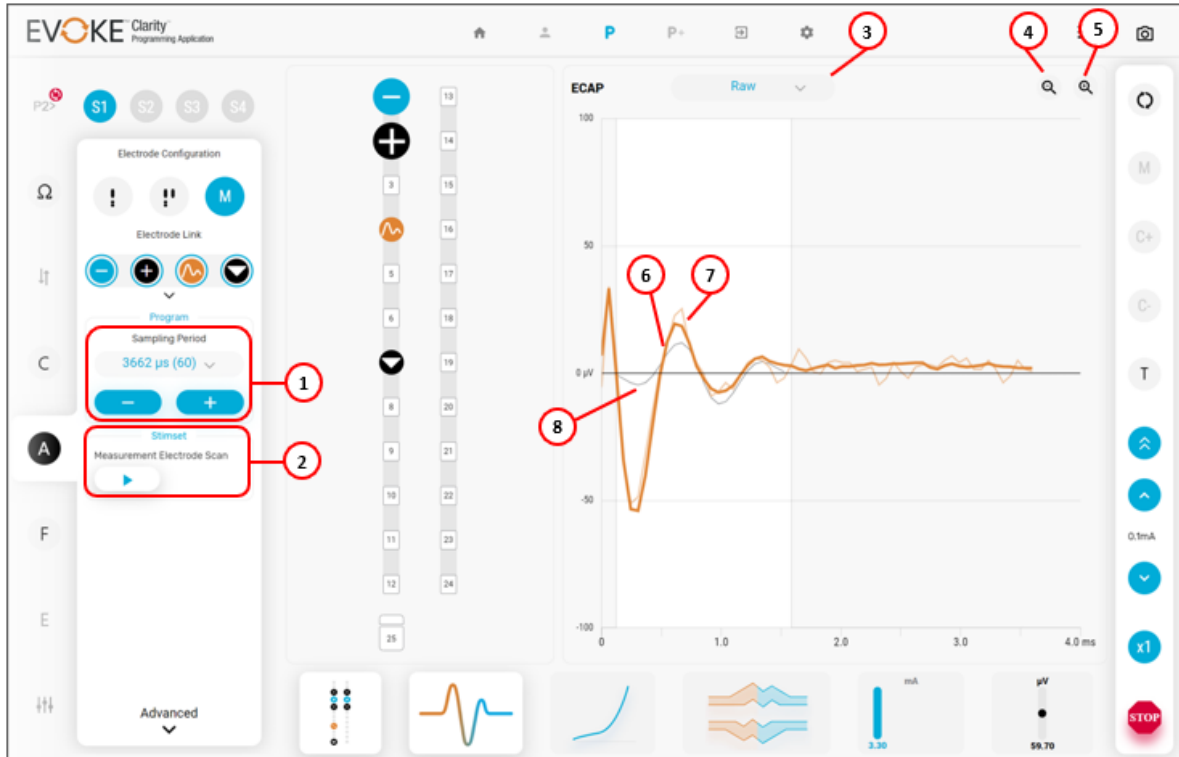
Figure 6.35: Acquisition tab with Electrode and ECAP displays visible

1. Sampling Period	3. ECAP display mode	6. Average ECAP signal (thick orange)
2. Measurement Electrode Scan (MES) start/stop	4. Zoom out (Y-scale)	7. Instantaneous ECAP signal (thin orange)
	5. Zoom in (Y-scale)	8. Correlation Filter used to measure (black)

When stimulation is running, a measurement electrode scan (MES) of up to 4 different measurement electrode configurations may be displayed on the ECAP display. Refer to Section 6.4.5.3 for more information on using MES to optimize the choice of measurement electrodes and settings.

To optimize the ECAP measurement:

1. Start stimulation and increase the stimulation current so that a clear ECAP signal is visible and/or above the patient's perception threshold.
2. Use the ECAP display and measurement electrode scan to determine the measurement electrode configuration with the optimal ECAP based on size/shape.
   a. Enabling ClearCAP may improve ECAP measurement (see Section 6.4.5.4 for more information on ClearCAP).
3. Touch and drag the recording electrode to move as needed to optimize the ECAP signal.
4. Touch and drag the reference electrode to move as needed to optimize the ECAP signal.

6.4.5.1   *Settings in Acquisition and Acquisition→Advanced*

See Section 7.3 for more information about each setting.
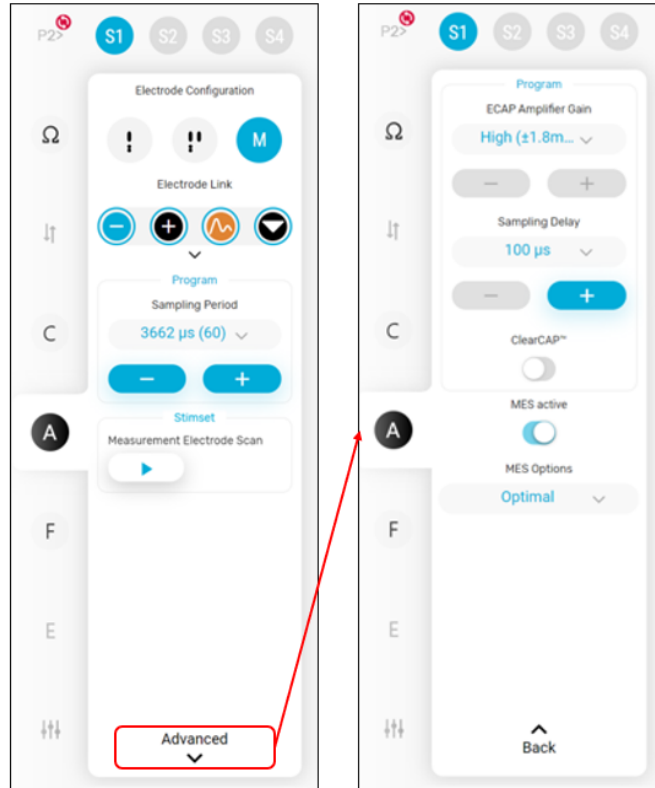
Figure 6.36: Acquisition tab and the Advanced options.

a. **Sampling Period**

   The number of samples of the signal to record. The Sampling Period must be greater than or equal to the Processing Offset plus the Processing Period. Consider increasing this if the ECAP signal cannot be optimally measured (i.e. the filter cannot be optimally aligned and/or the complete ECAP signal cannot be seen in the ECAP display).

b. **Sampling Delay**

   The amount of time for the system to wait, following the stimulus pulse, before recording the signal. Consider increasing this from default (100 µs) if the Processing Offset cannot be increased enough for optimal measurement of the ECAP.

c. **ECAP Amplifier Gain**

   The voltage range of the signal that can be recorded. The default setting is 'High (± 1.8mV)'. Consider setting this to 'Low (± 7.2 mV)' if the ECAP signal is clipping.

d. **MES Toggle and MES Options** (see Section 6.4.5.3).

e. **ClearCAP** disable/enable (see Section 6.4.5.4).

6.4.5.2 *ECAP display and artifact estimation*

The signal recorded by the stimulator is a combination of the ECAP, artifact from the stimulation pulse, and background electrical or neural noise. The artifact is a signal resulting from the

stimulus pulse that is not related to neural activity, but can interfere with measurement of an ECAP.

The CPA estimates the ECAP and artifact from the recorded signal so that an ECAP estimate may be displayed with the artifact and noise removed.

The ECAP display shows signals from up to 4 measurement configurations represented by 4 colors (see Section 6.4.5.3). The display shows the 'latest' from one stimulation, 'average' from 16 of those measurements and an 'estimate' of the artifact component of the signals.

Select the drop-down menu at the top of the ECAP display to select amongst three modes of ECAP display: Raw, Scrubbed (simple) and Scrubbed (detailed).

A) **Raw**
- latest recorded signal (light line)
- average recorded signal (dark line)
- average artifact estimate (thin line)

B) **Scrubbed (simple)**
- average ECAP estimate (dark line)

C) **Scrubbed (detailed)**
- latest ECAP estimate (light line)
- average ECAP estimate (dark line)
- average recorded signal with average artifact estimate subtracted (dashed line)

6.4.5.3   *Measurement electrode scan (MES)*

The ECAP display shows the average ECAP estimate for each measurement electrode configuration and the correlation filter used to measure the ECAP. The ECAP display shows the currently in use (orange) and additional recommended (blue, green, purple) recording and reference electrode configurations.
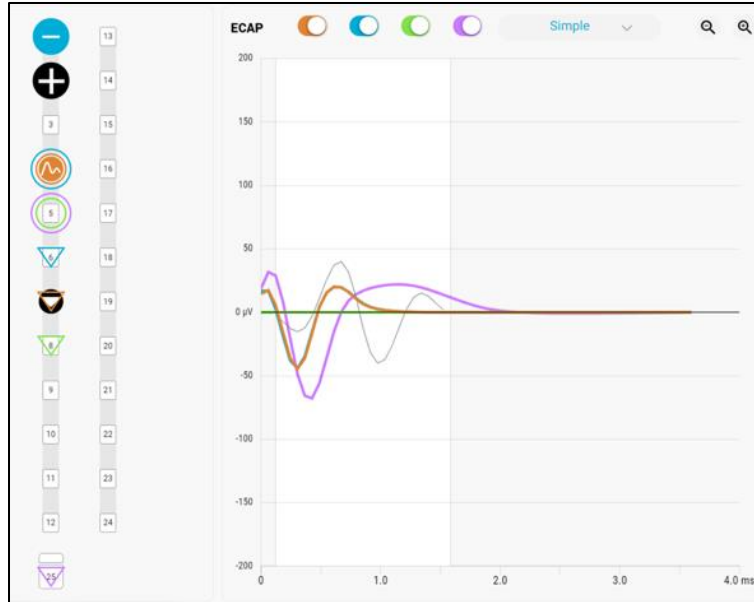
Figure 6.37: ECAP display and Electrode display showing the currently in use measurement electrode configuration (orange) and 3 other configurations (blue, green, purple).

MES allows ECAPs from multiple measurement electrode pairs to be displayed on the ECAP display (Figure 6.38) at the same time. It is intended to assist in optimizing the choice of measurement electrodes. By default, MES will automatically start when stimulation is started.
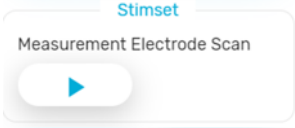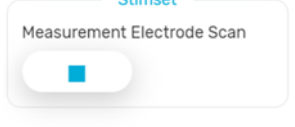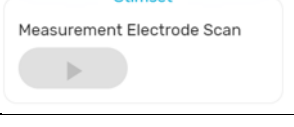
MES displays up to four configurations: the configuration programmed by the user, and up to 3 other configurations recommended by the system. Each can be added/removed from the display using the toggles at the top of the ECAP display when it is maximized.

The measurement electrodes used in the scan are based on the location of the stimulation electrodes, as well as the recording and reference electrodes that have been programmed by the user.

The recommended measurement settings are calculated from the average recorded signal when the ECAP display is in the raw mode and from the ECAP estimate when in the scrubbed modes.
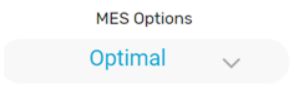
To enable MES:

- The programmed stimulation and measurement electrodes must be on the same lead.
- Neither of the measurement electrodes can be adjacent to a stimulation electrode.
- A measurement electrode cannot be on the case (E25).
- The recording electrode ⬤ must be between the stimulation and reference electrodes

Button	Action
Stimset Measurement Electrode Scan ▶	Stop or Start the measurement electrode scan while stimulation is running. This does not change the automatic start of the scan when stimulation is started. *Note these buttons are greyed out if MES is disabled.
Stimset Measurement Electrode Scan ■	
Stimset Measurement Electrode Scan ▶	

MES settings

1. Within the Acquisition tab, Touch **Advanced ⌄** to open additional setting options.

Button	Action
MES Options Optimal ⌄	Choose the method used to select up to 3 electrode configurations to be used in the scan These configurations are in addition to the user selected configuration (for examples see):

Button	Measurement	Reference
*Optimal** (#electrodes from stimulation/cathode)	3 3 4 4	5 6 7$^+$ case (E25)
*Fixed Reference^* (#electrodes from selected)	1 closer‡ 1 further 2 further	As selected
*Fixed Measurement^* (#electrodes from selected)	As selected	1 closer 1 further 2 further
*Fixed Distance^* (#electrodes from selected)	1 closer‡ 1 further 2 further	1 closer 1 further 2 further

Button	Action
MES active ◯	Disable or Enable the measurement electrode scan for the duration of the programming session. When disabled, the measurement electrode scan will not be automatically started when stimulation is started.

*Note: Default**.** For *Optimal,* if an electrode is disconnected, that configuration will be skipped.

^**Note:** For *Fixed,* if an electrode is disconnected, that configuration will be skipped and the next electrode further from the stimulation electrode will be used until the end of the lead is reached, or the reference electrode is reached for *Fixed Reference*.

⁺**Note:** For this configuration, if the stimulation electrode is on E6 or E7, then the reference electrode will be 6 electrodes from stimulation instead of 7.

‡**Note:** Configurations with the measurement electrode adjacent to the stimulation electrode will be skipped.

Optimal				*Fixed Reference*				*Fixed Measurement*				*Fixed Distance*			
+E6	+E5	+E5	+E6	+E6	+E5	+E7	+E8	+E6	+E6	+E6	+E6	+E6	+E5	+E7	+E8
-E9	-E7	-E8	-E25	-E9	-E9	-E9	-E9	-E9	-E8	-E10	-E11	-E9	-E8	-E10	-E11
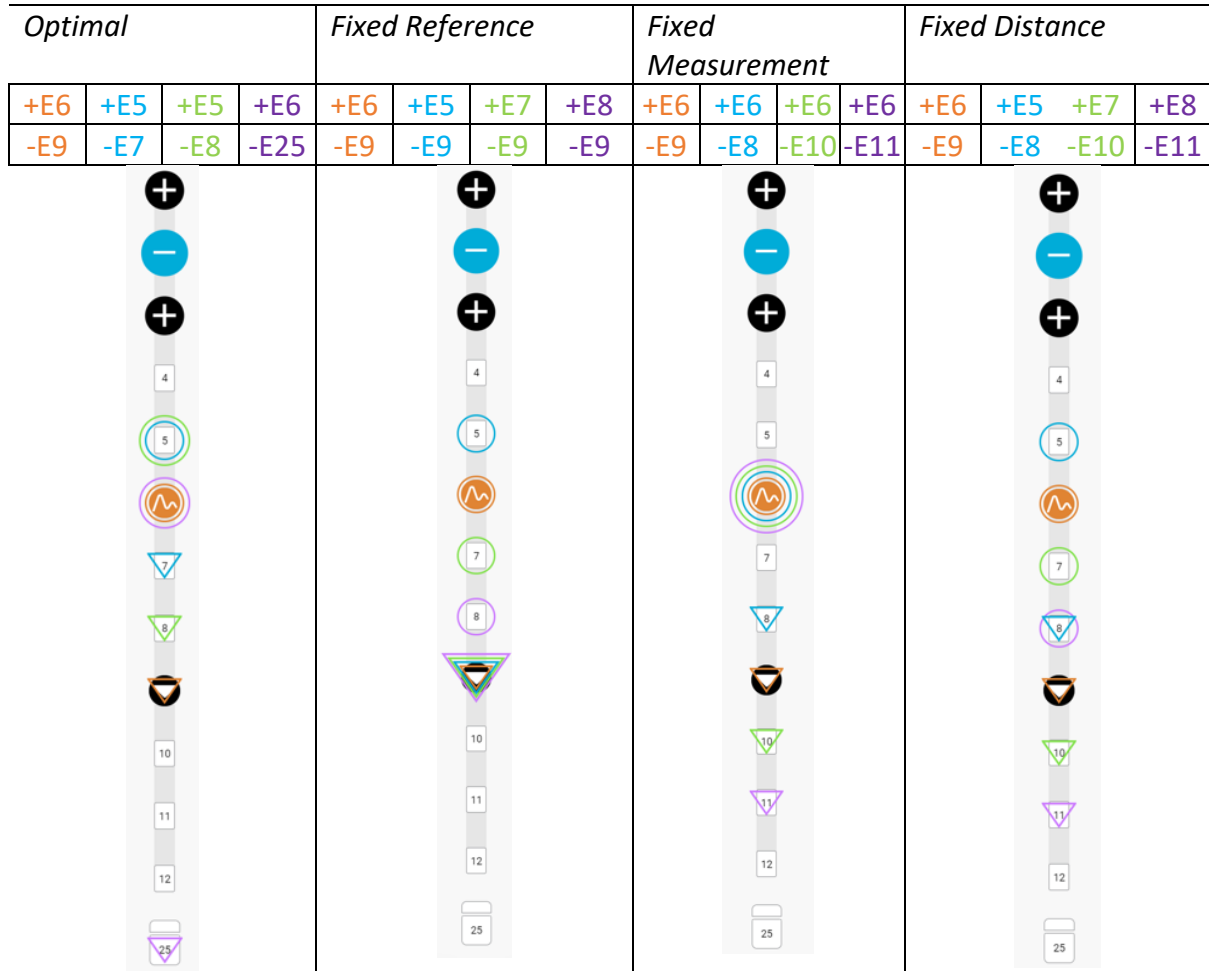
Figure 6.38: Examples of Measurement Electrode Scan position configuration methods when the stimulation electrode (cathode) is at E2.

6.4.5.4 *ClearCAP*

ClearCAP is used to reduce the artefact recorded during measurement by cancelling the artefact from the stimulation and return electrodes; this feature is best used when optimizing ECAP measurement. The Reference electrode ⬇ is colored differently (with a blue triangle) ⬇ when ClearCAP is enabled, however, the measurement functionality of the Reference electrode remains unchanged. ClearCAP may be enabled or disabled for each program.

Note: ClearCAP cannot be enabled or disabled during stimulation.

⚠️ **Caution**: The case electrode (E25) should not be used as the Reference electrode if ClearCAP is enabled.

⚠️ **Caution**: If the Measurement or Reference electrode is within 2 electrode spacings from a stimulation or return electrode, ClearCAP may not perform optimally.

In order to assess performance, comparing stimulation with and without ClearCAP (all other settings unchanged), ensure the following are true:

- Artefact magnitude should be reduced with ClearCAP enabled (see Figure 6.39).

- ECAP amplitude variability should be unchanged or reduced with ClearCAP enabled.

- Criteria described elsewhere in this section are still met with ClearCAP enabled.

  Note: If the criteria above cannot be met, ClearCAP should be disabled for the current program configuration.
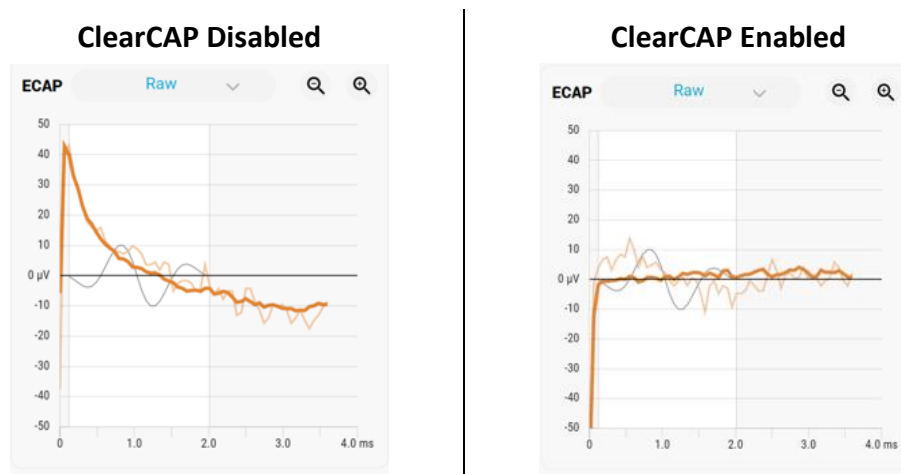
Figure 6.39: ECAP Display showing an example of artefact magnitude with ClearCAP disabled and subsequently decreasing when ClearCAP is enabled.

6.4.6 Filter Tab

Touch on the **Filter** tab on the left column navigation to fit the filter and amplify the ECAP signal by reducing artifact and noise. It is recommended that the **Activation Plot**, and **ECAP** displays are selected to view on the CPA screen.
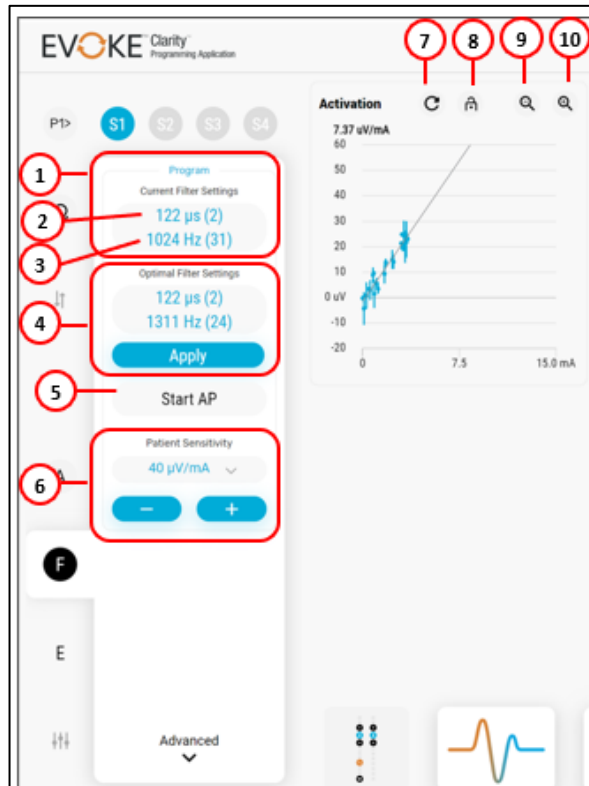
1. Current Filter Settings
2. Processing Offset
3. Filter Frequency
4. Optimal Filter Settings
5. Start AP (Activation Plot)
6. Patient Sensitivity
7. Clear AP
8. Lock AP
9. Zoom out
10. Zoom in

Figure 6.40: Filter tab layout.

1. Touch the **Apply** button to set the optimal filter settings for processing offset and filter frequency.
2. Ensure the applied (current) filter settings match the recommended optimal filter settings (Figure 6.41), and check that the peaks of the ECAP signal line up with the peaks of the correlation filter. If they don't, you may manually adjust Processing Offset and Filter Frequency until they do.
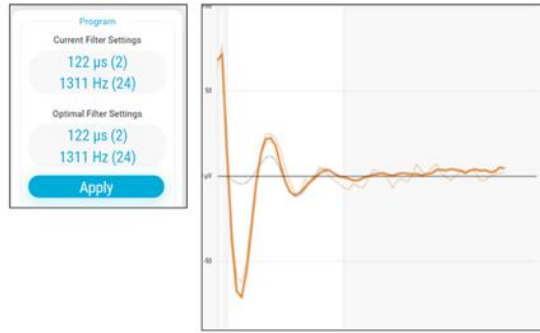
Figure 6.41: ECAP display with a well-matched filter (-).

Note: The default filter has a negative first peak (Figure 6.41). In some cases, filter alignment may be improved by flipping the filter the first peak is positive. This is done by changing the measurement type to 'Filter (+)' from the Measurement Type dropdown in Filter Tab → Advanced (Figure 6.42).
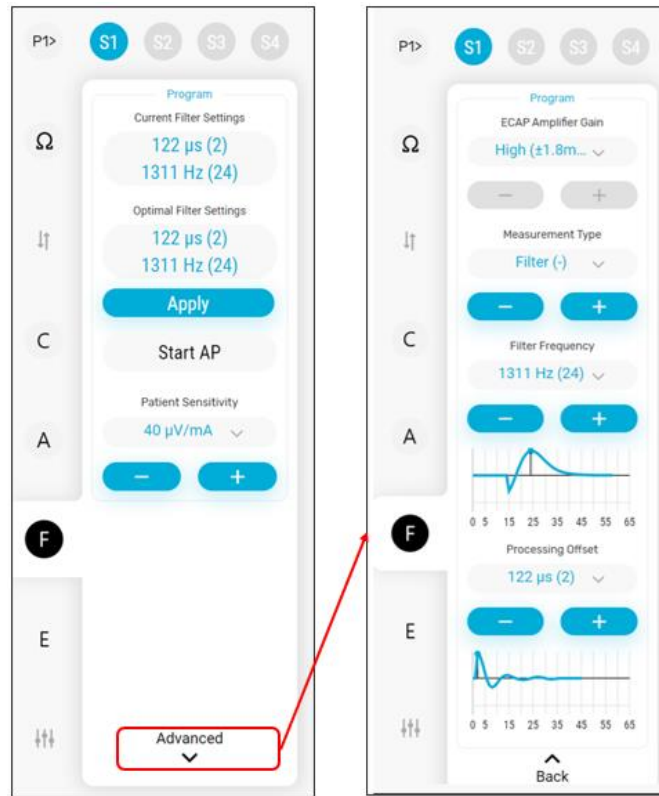
Figure 6.42: Filter Tab → Advanced.

3. To manually adjust the processing offset and filter frequency go to Filter Tab→Advanced. The blue dot on the plot is the recommended (peak of plot), while the black line is the setting in use.

4. There are four measurement type options in Filter Tab → Advanced (Figure 6.42):

a. ECAP Sampling Disabled

The ECAP recording is disabled for stimulation frequency greater than 250Hz. This option is not available for stimulation frequency less than or equal to to 250Hz

b. ECAP Measurement - filter (+)

The ECAP amplitude is measured using a correlation filter with peaks aligned with the ECAP signal. The first peak is positive and the Processing Period and Filter Frequency are adjusted to align the filter. The ECAP signal is also recorded and displayed in the ECAP display. For this option, closed-loop may be enabled, and stimulation frequency is available up to 200Hz.

c. ECAP Measurement - filter (-) [default setting]

The ECAP amplitude is measured using a correlation filter with peaks aligned with the ECAP signal. The first peak is negative and the Processing Period and Filter Frequency are adjusted to align the filter. The ECAP signal is also recorded and displayed in the ECAP display. For this option, closed-loop may be enabled, and stimulation frequency is available up to 200Hz.

d. ECAP Measurement - Amplitude

The ECAP amplitude is measured from the peak-to-peak amplitude of the ECAP signal within the Processing Period, aligned such that it contains the ECAP peaks and there will be no optimal filter settings. For this option, closed-loop may be enabled, and stimulation frequency is available up to 250Hz.

Note: This option should only be used with closed-loop enabled where the peak-to-peak amplitude is not affected by artefact.

6.4.6.1 *Measure activation plot and therapeutic window*

The settings for closed-loop stimulation vary between patients and for different electrode configurations. These settings depend on the sensitivity of the ECAP to changes in current.

The CPA can measure ECAP sensitivity as the current is varied in the Activation Plot display, following these steps:

1. Ensure you have optimized the ECAP measurement (refer to Section 6.4.6).
2. Measure the Activation Plot.
   a. Mark the activation plot levels by touching the following buttons (see Figure 6.43):
      - *Threshold* (**T**): ECAP threshold or when the patient first feels a change in sensation (e.g. paresthesia or pain relief).
      - *Comfort* (**C-** and **C+**): When the patient reports a preferred comfortable sensation, for increasing or decreasing stimulation, respectively.
      - *Maximum* (**M**): When the patient could tolerate stimulation for no more than approximately one minute.

   Note: When marked, the button turns blue.

Note: The levels will be indicated by horizontal lines on the Current (mA) and ECAP Amplitude (µV) displays, and horizontal (ECAP amplitude) and vertical (current) lines on the activation plot display (Figure 6.43). They will also be recorded as notes in the programming data, and screenshots in the Notes window.

3. The therapeutic window is defined by the difference between the ECAP amplitudes at Threshold (T) and Maximum (M). Only enable closed-loop if the therapeutic window is > 10 µV.

4. To change the levels, touch the button once to clear the mark, then touch again to set the mark to the new level.

   Note: The Threshold level must be less than all other levels and the Maximum level must be greater than all other levels. If an activation plot level is selected that causes a previously selected level to fall outside these criteria, then the previously selected mark will be cleared (e.g. If **C+** is selected at a level less than **T**, then the mark for **T** will be cleared).

   Note: The levels will be cleared if settings are changed that could affect the activation plot levels (e.g. if pulse width is changed, stimulation current and ECAP amplitude levels will be cleared; if processing offset or filter frequency are changed only ECAP amplitude levels will be cleared).

   b. Touch the *Ramp Up* ⊗ button to gradually increase the stimulation current or ECAP Target to the next activation plot level or the level when stimulation was last stopped.

   ⚠️ **Caution:** If the patient reports that stimulation is getting stronger than expected due to, for example, a change in posture:

   - Stop stimulation by pressing the *Stop* button 🛑, or

   - Stop the ramp up by pressing the *Increase* 🔵 or *Decrease* 🔵 buttons.

   Note: The CPA cannot ramp to the **M** level that was set.
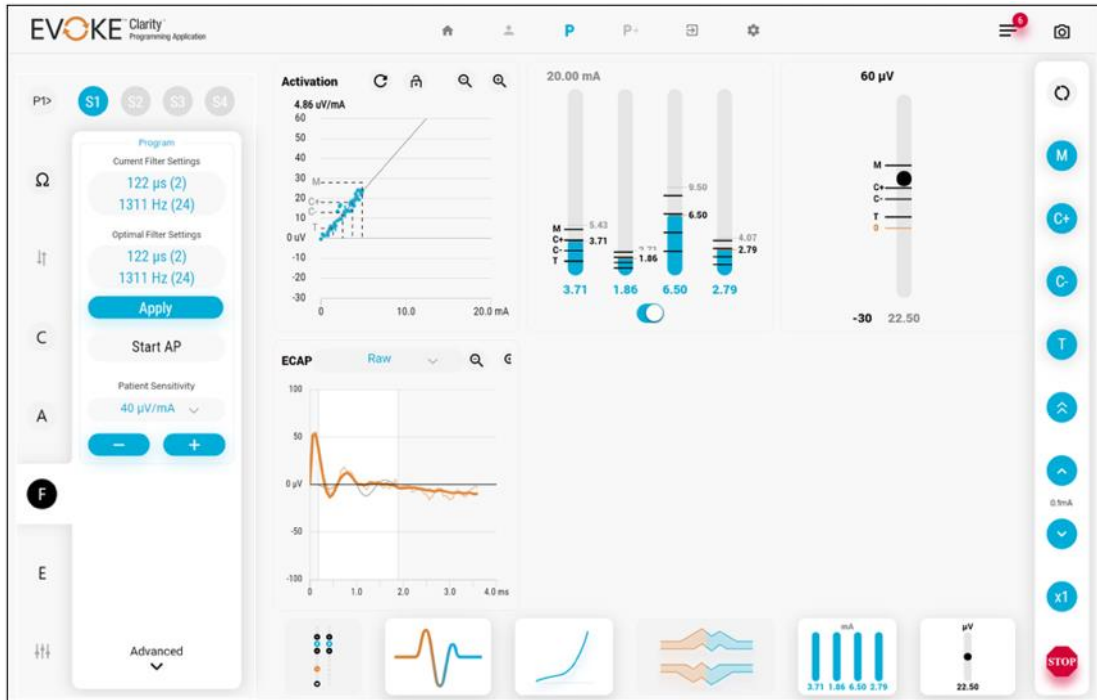
Figure 6.43: Filter Tab with Activation, ECAP Amplitude, Current Amplitude, and ECAP display. The **Ramp Up, M, C+, C-** and **T** buttons are on the right control panel.

5. The activation plot display shows the ECAP amplitude as a function of current, and the measured sensitivity is displayed on the plot (Figure 6.44).

6. Ensure that the displayed activation plot meets the following criteria:

   a. The activation plot should show an obvious inflection in the ECAP amplitude close to the patient's paresthesia threshold. Above this inflection the ECAP amplitude should increase linearly with the stimulation current.

   b. The therapeutic window should be >10 μV.

   c. The measured sensitivity should be >10 μV/mA.

   Note: If a Measured Sensitivity value does not appear then decrease the current increment and repeat steps 2-4 above.

⚠️**Caution:** Closed-loop may not operate as intended if the activation plot does not meet these criteria. Do not enable closed-loop operation until the above criteria are satisfied.

7. If the activation plot does not meet the above criteria you will need to improve the signal quality by adjusting the ECAP measurement settings (see Section and 6.4.6) and/or adjusting the stimulation settings (see Section 6.4.4).
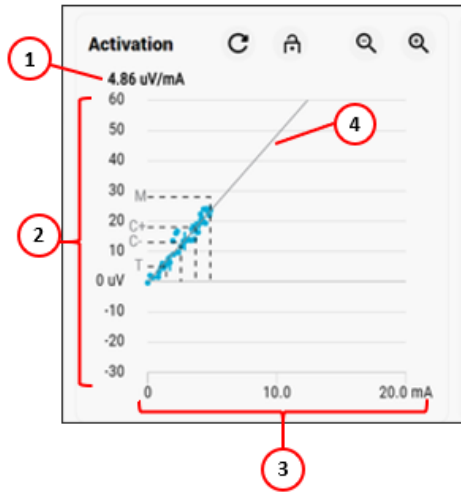
6. Measured sensitivity
7. ECAP measurement axis (µV)
8. Stimulator output current axis (mA)
9. Estimated slope of AP (gray line)

Figure 6.44: Activation Plot (AP) Display.

8. If the criteria for the activation plot are met, select the patient sensitivity value that is closest to the measured sensitivity value, rounded up in the Filter tab. The minimum patient sensitivity is 14 µV/mA.

6.4.7 Evaluation Tab

Touch on the **Evaluation** tab once all the settings for the program have been set up and the criteria for the activation plot have been met to evaluate closed-loop operation. It is important to test the effectiveness of the closed-loop control with the patient in various postures.
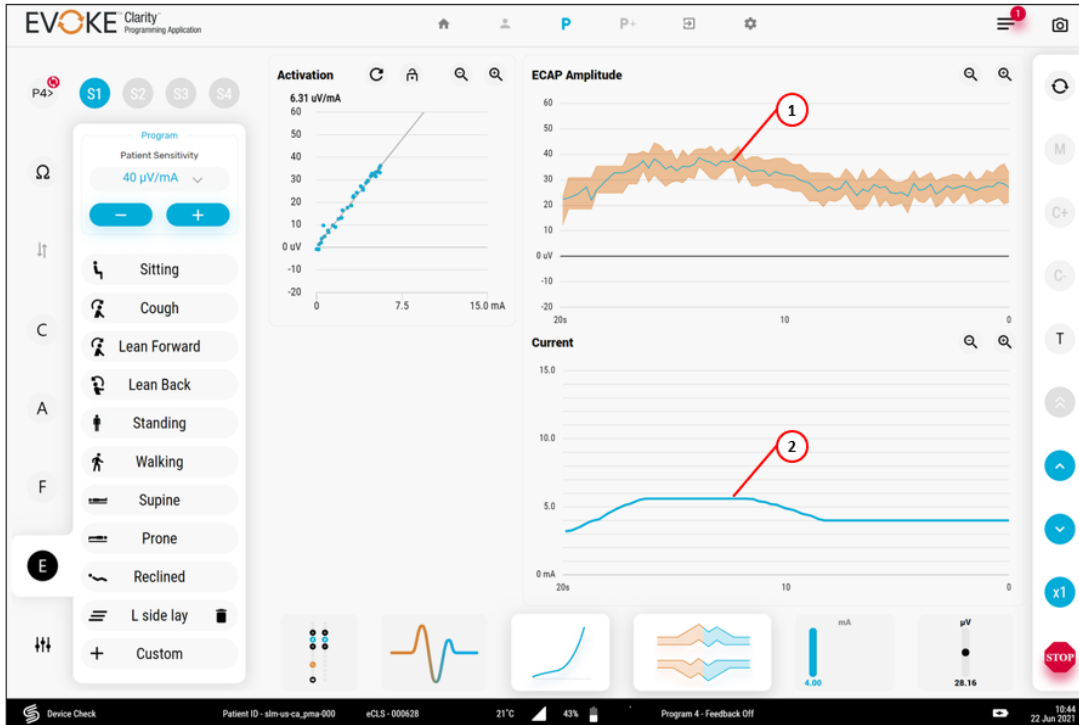
Figure 6.45: Evaluation Tab with Rolling Plot and Activation Plot display. Closed-loop is disabled.

1. ECAP rolling plot (blue line in Closed-loop disabled)
2. Current rolling plot (blue line in Closed-loop disabled)

To evaluation the effectiveness of the closed-loop stimulation:

1. Start stimulation and set the current to a comfortable level.

2. Touch the ⟳ icon to enable closed-loop stimulation on the right control panel. When closed-loop is enabled the icon will turn orange ⟳ .

3. When closed-loop is enabled, the ECAP amplitude rolling plot and Current rolling plot line graphs will change from **blue** to **orange** (Figure 6.46). Various elements and buttons on the CPA will also turn **orange** to signal that closed-loop is enabled. The current will also vary over time. The ECAP amplitude will vary around the target. If the ECAP variability is increased after closed-loop is enabled:

   a. You may increase the Patient Sensitivity setting to reduce this variability.

   b. If the measured sensitivity is low (near 10 µV) and the stimulation frequency is low (e.g. 10-20 Hz), try increasing the stimulation frequency to reduce the variability. If you change the stimulation frequency, you will need to check the ECAP measurement and re-measure the activation plot (repeat the steps from Section 6.4.6 onwards).
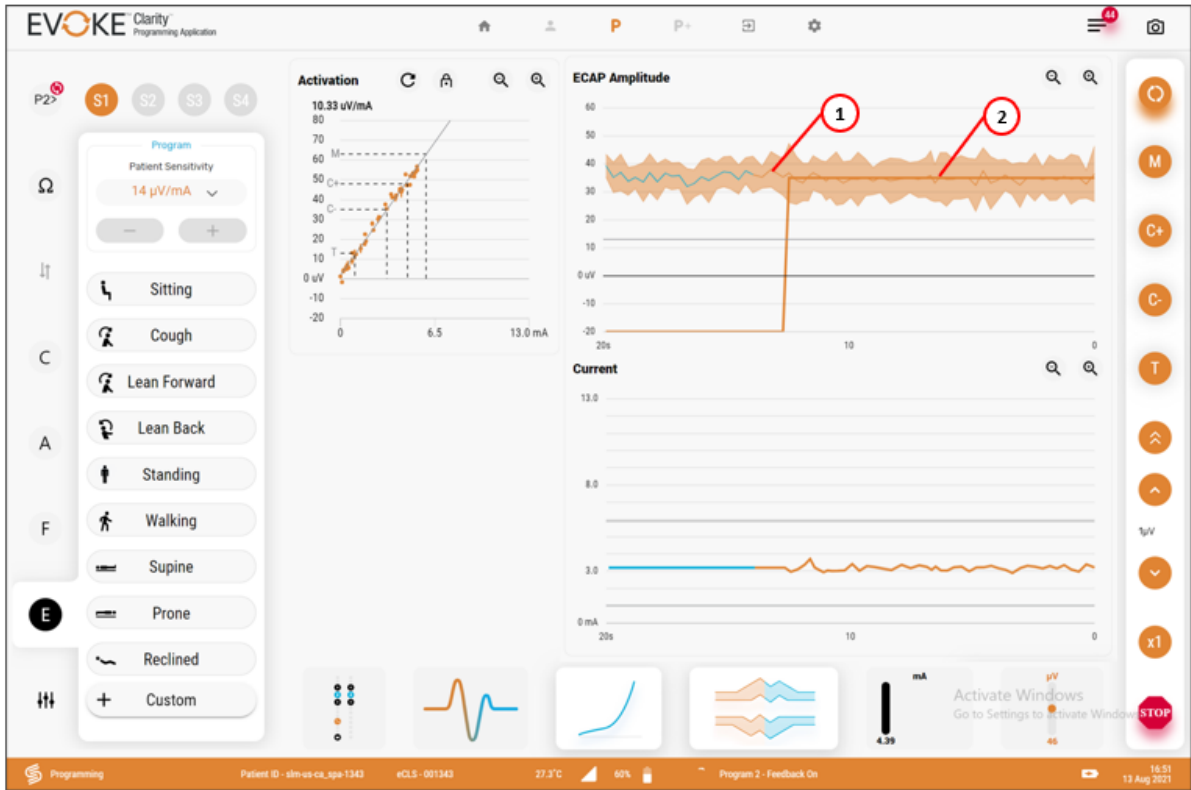
Figure 6.46: Evaluation tab showing transition from closed-looped disabled to closed-loop enabled in the Rolling Plot display.

1. ECAP amplitude rolling plot (thin orange line)
2. ECAP amplitude target (thick orange line)

4. Monitor the rolling plot through various postures. Ask the patient to move into various postures such as sitting, standing and lying on their back (supine) while you watch the rolling plot to see how the closed-loop control responds. The ECAP amplitude will show some variability, but the average ECAP amplitude should track the target level, and changes in current should track the patient's movement (Figure 6.46). If they don't, you may need to adjust the acquisition or filter settings (see Section 6.4.5 and 6.4.6 respectively).

5. During the posture changes, if the patient reports large changes in stimulation intensity when they change postures, you may decrease the Patient Sensitivity setting. If the patient reports discomfort with stimulation sensation while they are not moving, you may increase the Patient Sensitivity setting.

6.4.8 Program Settings Tab

The Program settings Tab includes general program parameters that aren't specific to the CAFE algorithm, which includes limits, increments and intervals.

- Refer to Section 7 for full details about all parameters listed.

6.4.8.1 *Set appropriate limits and increments*

1. Prior to final testing, appropriate limits and increments should be set for each program that the patient has saved to their stimulator.

2. Refer to Table 6.3 for guidelines on determining appropriate values.

3. The limits (both stimulation current and ECAP target minimum and maximum) should be tested to ensure that the stimulator has enough range to allow the patient to receive therapy at a comfortable level across a range of postures (e.g. leaning forward, leaning back, standing, sitting, and walking). If required, the limits should be adjusted accordingly.

4. The increments (stimulation current and ECAP target) should be tested above patient perception threshold to ensure that each step can be felt by the patient. These intervals should not be too large (e.g. significant changes in intensity) or too small (e.g. no noticeable changes in intensity), and adjusted accordingly if required.

Note: The settings may need to be adjusted following testing of each program.

Table 6.3: Guidelines for setting appropriate limits and increments for stimulation current and ECAP target.

Parameter	Guideline
Maximum Current Limit (mA)	Set to the first available value $\geq$1.5 x stimulation current at the Maximum activation plot level, measured while the patient is in the sitting posture).
ECAP Target Maximum (µV)	Set to the first available value such that the ECAP Target Limit > 0.67*Maximum and ECAP Target Limit > Comfort+, (where Maximum and Comfort+ refer to the activation plot levels measured while the patient is in the sitting posture)
ECAP Minimum (µV)	Set to the highest value such that the ECAP Minimum $\leq$ minimum ECAP amplitude recorded during collection of the activation plot and posture testing.
ECAP Target Minimum (µV)	Link to ECAP Minimum, or if necessary, de-link and set to the highest value such that the ECAP Target Minimum $\leq$ ECAP amplitude at the ECAP threshold.
Current Increment (mA)	Set between 0.1 and 0.2 mA, depending on the current range between Threshold and Maximum activation plot levels in the sitting posture. Increase the increment if each step has no noticeable change in intensity for the patient, and decrease the increment if there is too large a change in intensity.

ECAP Target Increment (µV)	Set to the value closest to Comfort+/10 (where Comfort+ refers to the activation plot level measured while the patient is in the sitting posture)

6.4.9 Adjusting stimulation with closed-loop enabled

Closed-loop stimulation may be increased/decreased and stopped using the same controls used when closed-loop is disabled. Rather than controlling the current, these controls will now control the ECAP amplitude target.   Touch the Stop button to stop delivery of stimulation current at any time.
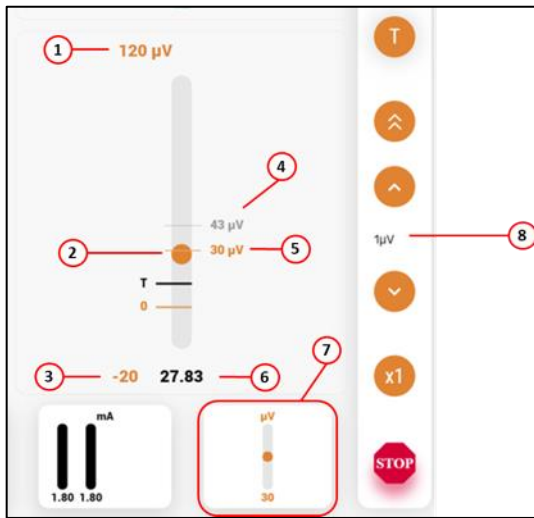
1. ECAP Target Maximum
2. Average ECAP amplitude (graphically represented)
3. ECAP Target Minimum
4. Previous Target (when stim was last stopped)
5. ECAP target
6. Average ECAP amplitude (numerically represented)
7. ECAP amplitude thumbnail, with ECAP target (in µV) displayed at the bottom.
8. ECAP target increment.

Figure 6.47: UI elements for ECAP amplitude control.

When the up/down buttons are clicked, the target will increase/decrease by the ECAP Target Increment (µV*)* set in the program settings tab (see Section 6.4.8). The ECAP Target Increment value is shown on the right control panel, between the up and down arrows. The ECAP target is displayed on the ECAP amplitude bar (#5) as well as on the ECAP amplitude thumbnail (#7). The average measured ECAP amplitude is represented on the ECAP amplitude bar by the orange disk (#2), as well as the number at the bottom of the amplitude bar (#6).

6.5 Neurophysiological Measurements Page

The CPA can be used with the eCLS/CLS to measure the neurophysiological characteristics of the patient's spinal cord, such as conduction velocity (CV) and chronaxie and rheobase (CR). These steps detail how to collect data for these measurements, via the Neurophysiological Measurements page.

6.5.1 Setup for neurophysiological measurements

1. Ensure the electrode configuration of the program to be used has been optimized for ECAP measurement.

2. From the Programming page, select any unused program (or any program that you don't plan to load settings from for the neurophysiological measurements). This program will need to be restored after completing these measurements, as will any other programs that you load from within the Neurophysiological Measurements page.

3. Touch **P+** to access the Neurophysiological Measurements page
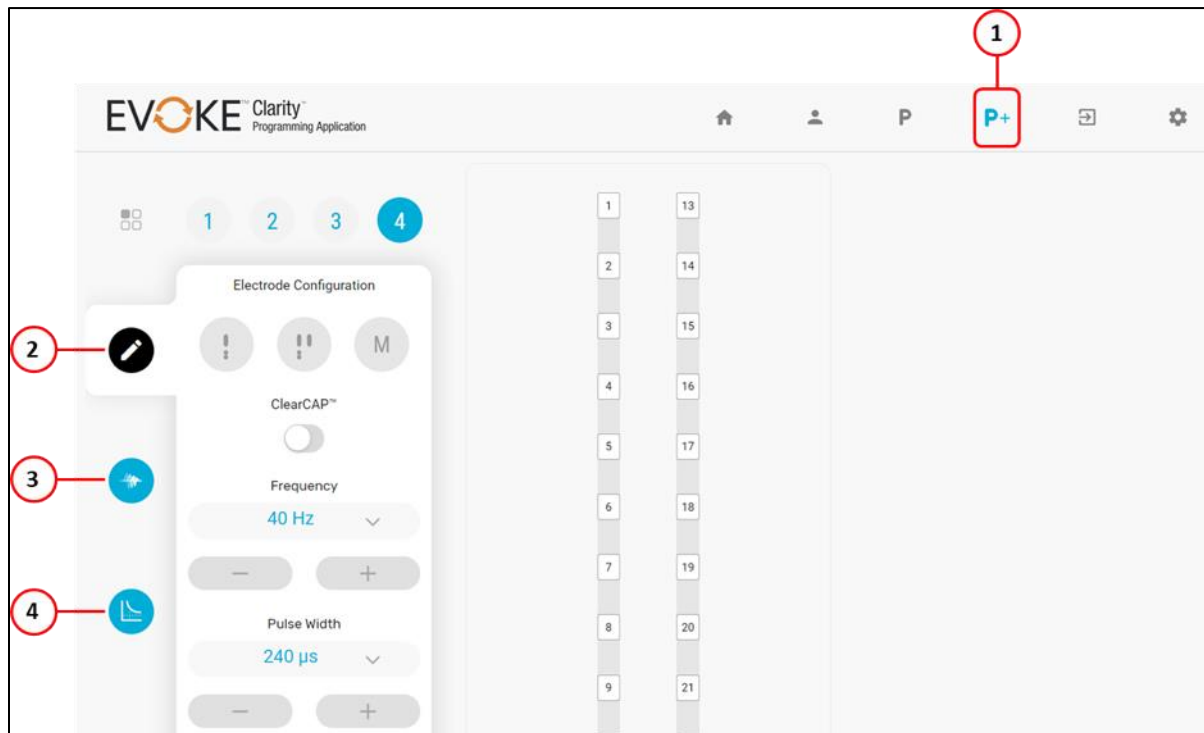
Figure 6.48: Layout of Neurophysiological Measurements Page (first tab).

1. Neurophysiological Measurements Page
2. Edit tab
3. Conduction Velocity (CV) tab
4. Chronaxie and Rheobase (CR) tab

6.5.2 Conduction velocity (CV) measurement

This is where you collect data to estimate the velocity at which elicited neural responses travel up or down the spinal cord. The CV measurement involves the CPA automatically moving the recording and (if applicable) reference electrodes at a fixed current level.

Figure 6.49: Layout of Conduction Velocity Tab.
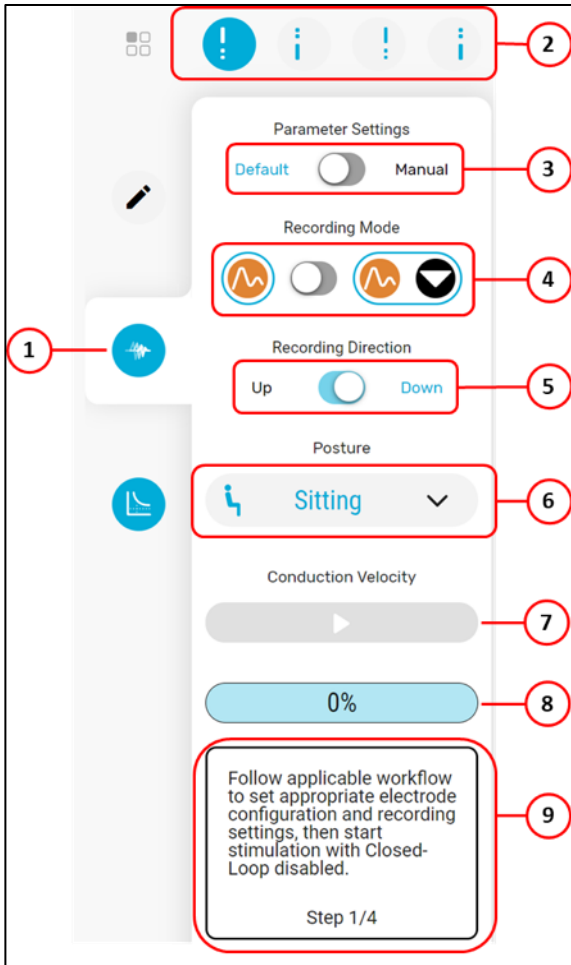
1. Conduction Velocity tab
2. Electrode Configuration options
    a. Stim at top of left lead
    b. Stim at bottom of left lead
    c. Stim at top of right lead
    d. Stim at bottom of right lead
3. Parameter Settings toggle
    a. Default(options above)
    b. Manual (settings made in Edit tab)
4. Recording Mode toggle
    a. Reference electrode (R-) is static
    b. R- moves w/ recording electrode.
5. Recording Direction toggle
    a. Up: recording electrode moves upward
    b. Down: recording electrode moves downward.
6. Posture drop-down
7. Start Measurement button
8. Measurement progress indicator
9. Workflow prompts

To perform a conduction velocity measurement:

1. After completing Setup (Section 6.5.1).
2. Touch the Conduction Velocity tab.
3. Choose the Electrode Configuration option to use.

   If you want to use an electrode configuration that is different from the default options provided, set the Parameter Settings toggle to Manual, and configure the electrodes via the Manual tab.

4. Select the Recording Mode to use.

   - *Fixed Reference* for recording configurations in which the reference electrode is to remain fixed (only the recording electrode will be automatically moved).

   - *Fixed Distance* for recording configurations in which the reference electrode is to remain a fixed distance from the measurement electrode (recording and reference will be automatically moved together).

5. Adjust the initial measurement electrode positions if needed.

- The recording electrode is usually placed near the stimulation electrodes (with a gap of at least 1 blank electrode).

⚠️ **Caution**: To avoid patient discomfort do NOT place the recording electrode directly adjacent to any stimulation electrodes (stimulation or return).

- For fixed reference recordings, the reference electrode is usually placed on the case electrode (E25), or on the end of the lead furthest from the stimulation electrodes.
- For fixed distance recordings, the reference electrode is typically placed 2 or 3 electrodes from the measurement electrode.

6. Set the Recording Direction for the direction that the measurement electrode should move.

7. Select the Posture that the patient is in, so that this note will be collected with the measurement data.

8. The Workflow Prompts will guide you through what to do next. Light blue highlights will indicate which button(s) the system is anticipating you to touch next.

   For example, if the C- button is highlighted 🔵, the workflow will proceed the next step when you have clicked the C- button.

9. Start stimulation with closed-loop disabled.

10. Ask the patient to remain still for the duration of the test, then increase the current until the patient reports that it is at a strong comfortable level, and touch the C- button.

11. Touch the **Start Measurement** button [▶] to begin data collection.

- The **Start Measurement** button will be replaced with a **Stop Measurement** button [■].
- Touch the **Stop Measurement** button at any time to end the measurement.

12. When the measurement is complete (or when it has been stopped), current will ramp down and off automatically.

13. To collect more measurements (e.g. with different configurations), return to Step 3 in this section.

14. After completion of the measurements, return to the Programming (P) page.

   The stimulation settings of each program will return to the state they were in before you entered the Neurophysiological Measurements (P+) page.

15. Start stimulation on any of the restored programs that have a sync icon to save the them to the stimulator again.

   This will ensure that the programs on the stimulator are set back to their original.

16. Use the RECAP Viewer to calculate conduction velocity using the data that was collected. Refer to Evoke SCS System RECAP Viewer User Manual for instructions.

6.5.3   Chronaxie and Rheobase (CR) measurement

This is where you collect data to estimate the chronaxie and rheobase of the stimulated neurons. The CR measurement involves the system automatically increasing and decreasing current at different pulse widths. You may stop stimulation at any time with the Stop button ![STOP].
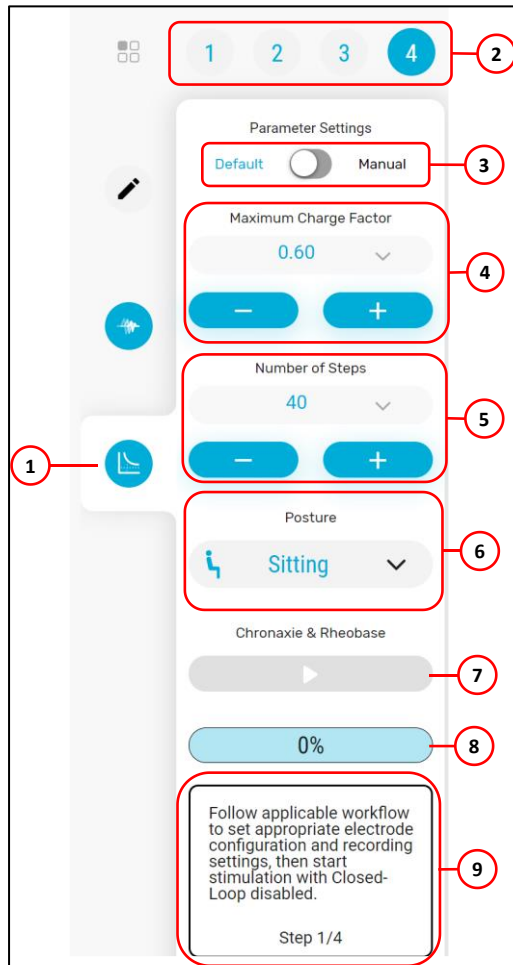
1. Chronaxie and Rheobase tab
2. Program selector
3. Parameter Settings toggle
    a) Default (standard CR options)
    b) Manual (changes made in Edit tab)
4. Maximum Charge Factor (MCF)—setting
5. Number of Steps—setting
6. Posture drop-down
7. Start Measurement button
8. Measurement progress indicator
9. Workflow prompts

Figure 6.50: Layout of Chronaxie & Rheobase tab.

To perform a chronaxie and rheobase measurement:

1. After completing Setup (see section 6.5.1).
2. Touch the Chronaxie and Rheobase tab.
3. Select the program number to use for the measurement. Only S1 will be used.
4. If you need to make modifications to the program settings:
    a. Set the Parameter Settings toggle to Manual.
    b. Touch the Edit tab.
    c. Make changes to electrode configuration and stim parameters as needed, as you

would in the Programming page. The PW used here will be the initial PW used for the CR measurement algorithm.
Note: The pulse width must be greater than 240µs.

d. Return to the Chronaxie and Rheobase tab.

5. Adjust the maximum charge factor if needed (default is 0.60). A higher chart factor will cause current to increase less when the PW is decreased throughout the measurements.

6. Adjust the Number of Steps to alter how quickly the measurement will take. Default is 40 steps. A lower Number of Steps will allow for faster measurements, but with fewer data points.

7. The Workflow Prompts will guide you through what to do next. Light blue highlights will indicate which button(s) the system is anticipating you to touch next.

   For example, if the C- button is highlighted , the workflow will proceed the next step when you have clicked the C- button.

8. Start stimulation with closed-loop disabled.

9. Ask the patient to remain still for the duration of the test and to inform you if the stimulation becomes too strong. Inform the patient that the stimulation current and pulse width will be automatically adjusted by the CPA during the measurement.

10. With the patient ready to begin, increase the current until the patient reports that it is at a strong comfortable level, and touch the C- button.

11. Touch the **Start Measurement** button to begin data collection.
    The **Start Measurement** button will be replaced with:

    Stop and **Pause** buttons .

    a. Touch the **Pause** button, at any time, to stop the current from changing.
       This may be required if the patient does not want the stimulation to increase any further.
       The **Stop** and **Pause** buttons will then be replaced with:

       Resume and **Next** buttons .
       The current will remain constant until you press one of those buttons.

       - Touch the **Resume** button to continue changing current in the same direction.

       - If current was increasing, touch the **Next** button to start the current decreasing (only do this if current was increasing). If you touch this button when current had already been decreasing, current will resume decreasing, and the measurement workflow will stop.

    b. Touch the **Stop** button to turn stimulation off and stop the chronaxie and rheobase measurement.

12. After completion of the measurement, return to the Programming (P) page.

    The stimulation settings of each program will return to the state they were in before you entered the Neurophysiological Measurements (P+) page.

13. Start stimulation on any of the programs marked as being out-of-sync.

   This will ensure that the programs on the stimulator are set back to their original

14. Use the RECAP Viewer to calculate chronaxie and rheobase using the data that was collected. Refer to Evoke SCS System RECAP Viewer User Manual for instructions.
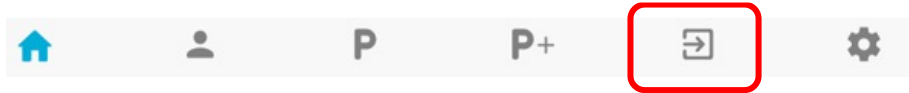
6.6 Disconnect Page

The Disconnect page is where you review your programming session, view any changes made, and confirm final program settings prior to disconnecting from the stimulator. Please refer to Section 6.4.3.1 for additional program color descriptions and Section 6.4.3.6 for additional Stim-Set color descriptions.
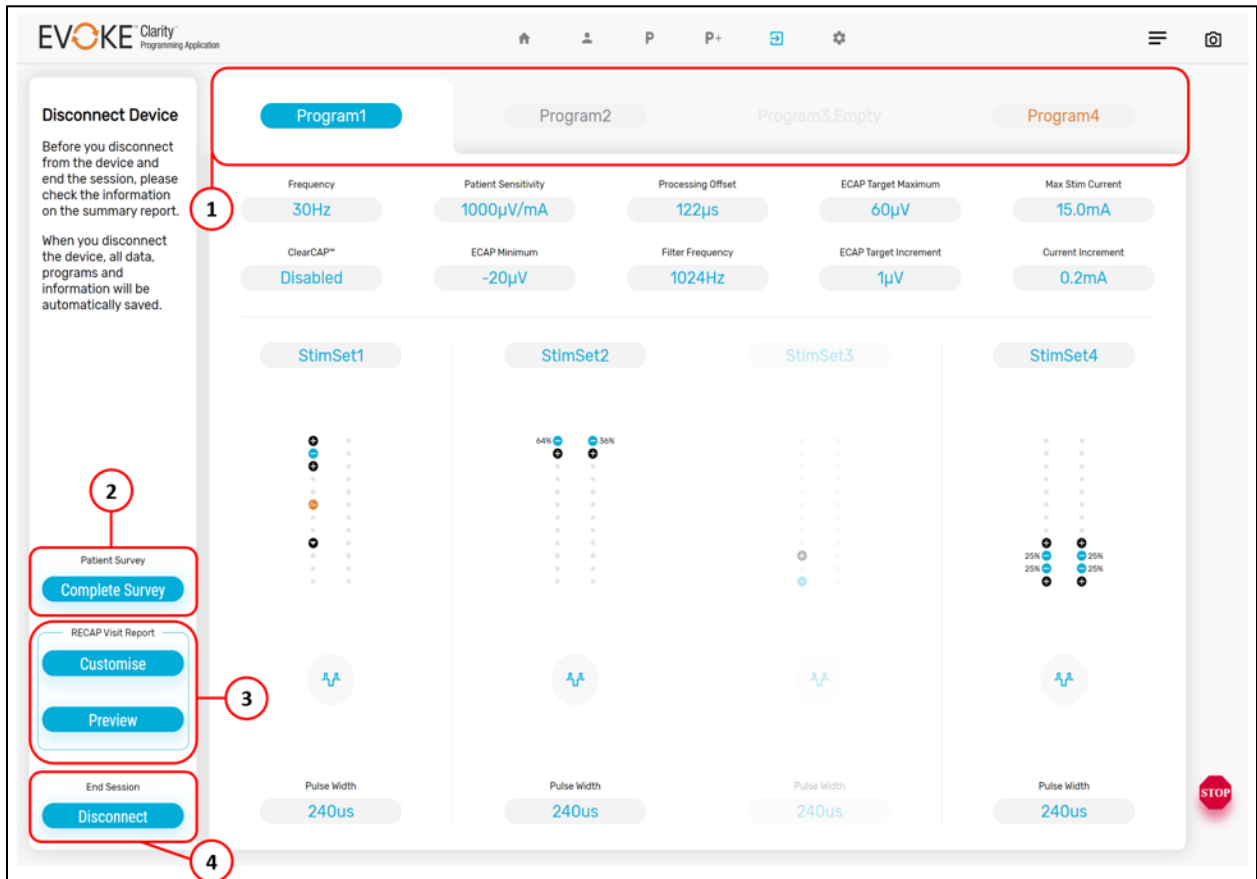
Figure 6.51: Disconnect Page Layout.

1. Final Programs   3. RECAP Visit Report
2. Patient Survey   4. End Session

Within the Disconnect page, there are three options to navigate to:

Patient Survey

1. Touch 'Complete Survey' if a survey was not already completed during the session. This will navigate you back to the *Patient* Page. Refer to Section 6.3.3 for more information.

RECAP Visit Report

2. Select 'Customize' to select the parameters to display in the final RECAP Report.
3. Select 'Preview' to generate the RECAP Report with default settings.

End Session

4. Select 'Disconnect' to disconnect from the device. Upon disconnection the programs on the CPA will automatically be saved to the corresponding visit folder on the CI and the session will be ended.

6.6.1 Customize RECAP Visit Report

Within the RECAP Report, you can customize the information that is shown on the RECAP Visit Report. Towards the left center of the screen, the sections of the RECAP Visit report are listed out. These sections are nominally set to the default.
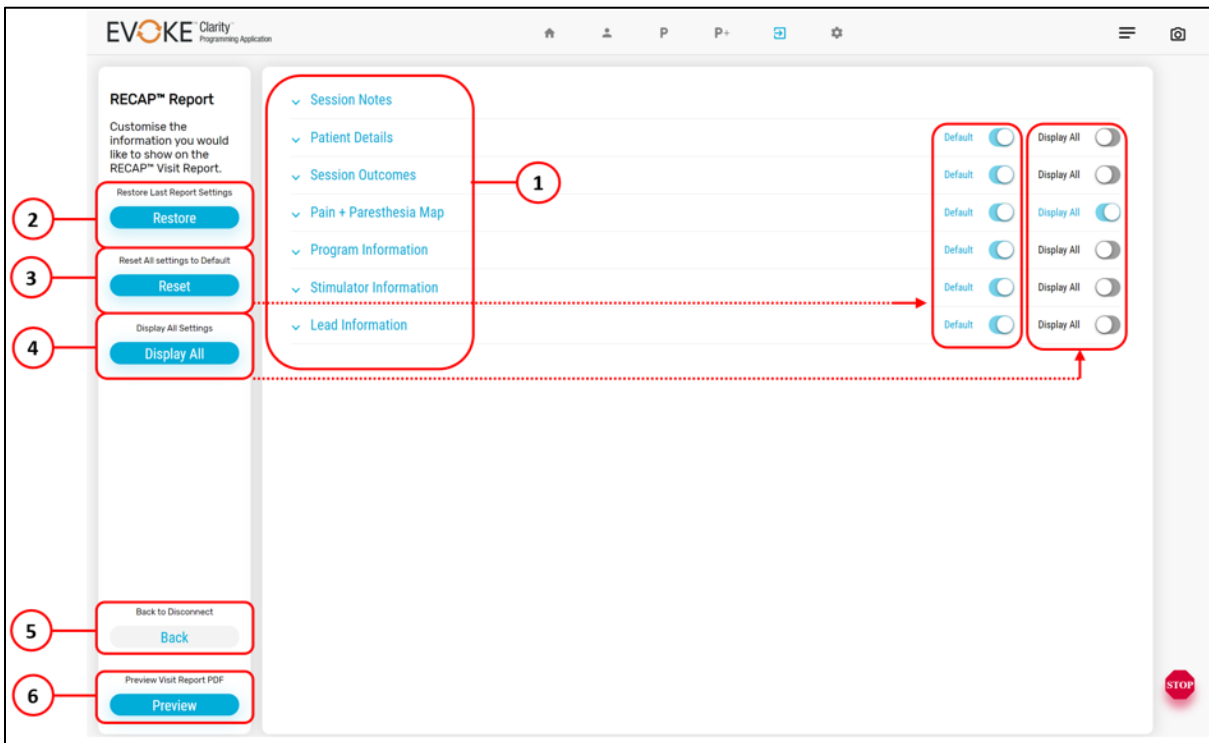
Figure 6.52: Customize RECAP Report Page Layout.

1. RECAP Report Sections	4. Display All settings

2. Restore Last Report Settings
3. Reset All settings to Default Visit

5. Back to Disconnect
6. Preview Visit Report PDF

Expanding and Selecting RECAP Visit Report Items

1. To see the entire list of what is in each section, select the carot ˅ or ˄ next to the header to expand or collapse.

Figure 6.53: Expanding/Collapsing RECAP Visit Report Sections.

2. The user can then customize the report to:

   a. Show the Default settings

   b. Display all settings,

   c. Restore last report settings

   d. Manually choose what is in the report.

3. Once you finish customizing the report, touch the 'Preview' button to generate the report.

6.6.2   *Preview RECAP Visit Report*

Verify that the RECAP Visit report is acceptable per the Clinician's Requirements. The RECAP Visit Report is generated from the programming changes (comparing the first connection in a day to the settings when the report is generated) and the latest patient survey that was filled out for the current visit date.
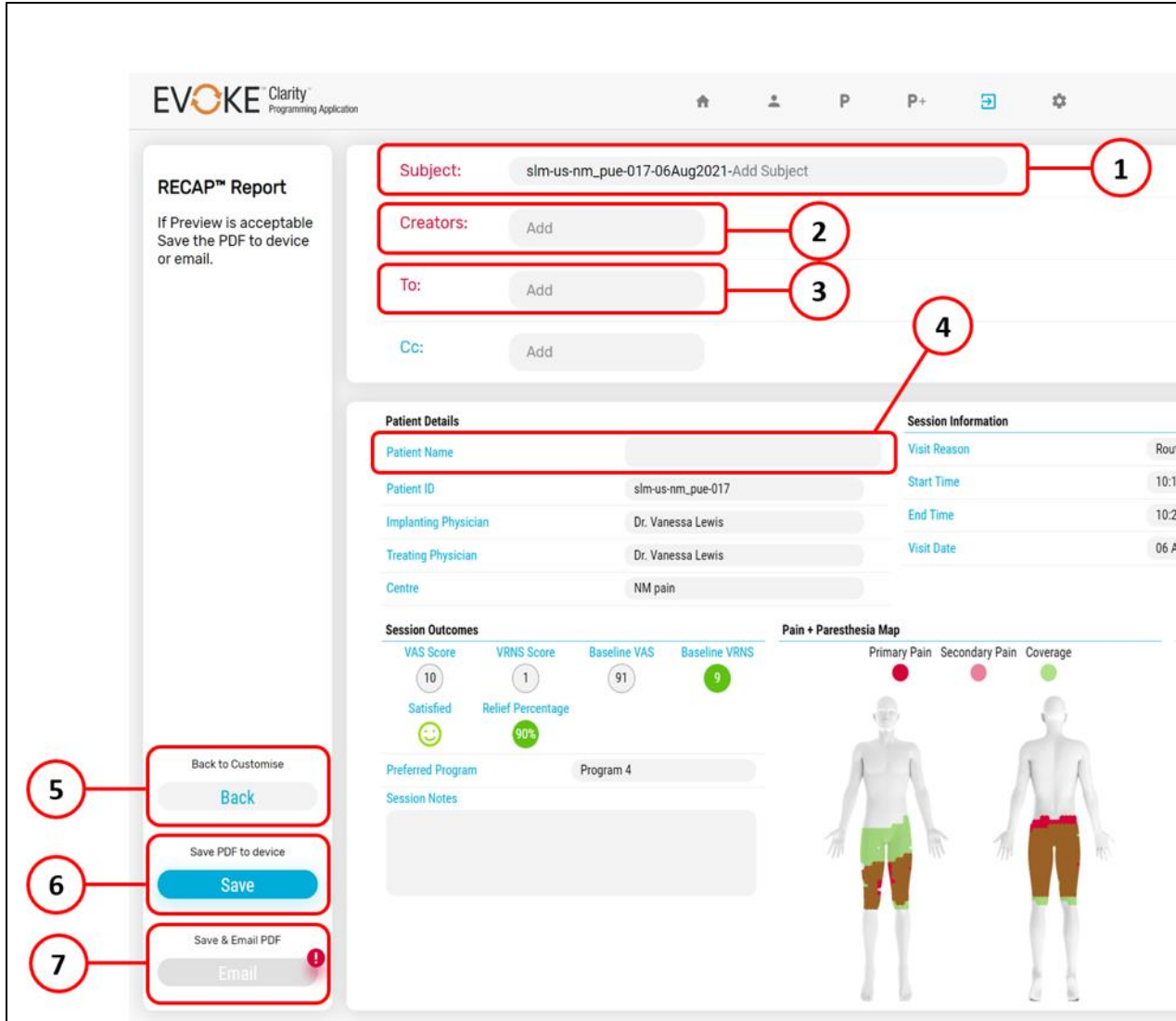
Figure 6.54: Preview RECAP Report Page Layout.

1. Subject: Add 'Email Subject'
2. Creators: Add 'Email address'
3. To: Add Recipient's 'Email address'
4. Add Patient Name
5. Back to Customize
6. Save PDF to device
7. Save & Email PDF

There are two options to select from: 'Save PDF to device' or 'Save & Email PDF'.

Save PDF to device

1. Touch 'Save'. The RECAP Visit Report will be saved to the CI as a PDF in the 'SaveFiles' folder (without any text in the 'Patient Name' field), for the corresponding Visit, and will automatically open in the installed PDF reader to ensure it looks as expected.

Save and Email PDF

1. If you plan to directly email the RECAP Visit Report to the clinician, fill out the

following sections (located at the top of the screen):

    a. **Subject**: e.g. 'RECAP Visit Report'.

    b. **Creators**: Email address of who is creating the report.

    c. **To**: Intended recipient(s).

* If these sections are blank or not properly filled out, the section's label font will be red and there will be an 🔴 over the 'Email' button.

2. All sections' label font will be blue and the 'Email' button will also turn blue once the file is ready to be emailed.

3. Touch 'Email'.

    a. The RECAP Visit Report will be saved to the CI as a PDF in the 'SaveFiles' folder (without any text in the 'Patient Name' field), for the corresponding Visit, and will automatically open in the installed PDF reader.

    b. You will get a notification that 'The RECAP report will be emailed with next upload!'.

    Note: The report 'Creator' will also be emailed a copy of the report.

4. Once you disconnect and exit the CPA, this report will be located within the 'SaveFiles' folder of the visit (see Section 6.6.3).

6.6.3 Navigating to RECAP Visit Report

Saved RECAP Visit reports are saved in the same folder as SaveFiles. See Section 6.7.1.1 for instructions on where these folders are located on the C: drive.

6.6.4 RECAP Visit Report

Below is an example of a RECAP Visit Report that 'displays all' information. Red boxes represent data that is obtained from this session's programming survey. Orange boxes represent data from the actual programming session and any changes that were made.

Additional Notes:

- Impedance – If impedance values are measured multiple times, the last measurement will be shown in the report.

- Programs – RECAP Visit Report will only show programs that are not empty.

- Program legend and Lead Information will be the same for every device.

- ClearCAP is represented by the change to the reference electrode 🔽 .

8/6/2021
Clarity Programming Application

Patient Details

Patient ID	slm-us-nm_pue-017
Implanting Physician	Dr. Vanessa Lewis
Treating Physician	Dr. Vanessa Lewis
Centre	NM pain

Session Information

Visit Reason	Routine programming
Start Time	10:17
End Time	10:28
Visit Date	06 AUG 2021

Session Outcomes

| VAS Score | VRNS Score | Baseline VAS | Baseline VRNS |
| 10 | 1 | 91 | 9 |

Satisfied — ☺
Relief Percentage — 90%

Preferred Program — Program 4

Session Notes

Pain + Paresthesia Map

Primary Pain ● Secondary Pain ● Coverage ●

Impedance

>4000 High   <50 Short   Disconnect

491 Ω	1	13	482 Ω
482 Ω	2	14	491 Ω
482 Ω	3	15	482 Ω
491 Ω	4	16	491 Ω
491 Ω	5	17	491 Ω
491 Ω	6	18	491 Ω
491 Ω	7	19	491 Ω
491 Ω	8	20	491 Ω
491 Ω	9	21	482 Ω
491 Ω	10	22	491 Ω
491 Ω	11	23	491 Ω
491 Ω	12	24	491 Ω
		25	

8/6/2021   Clarity Programming Application

Program 4 ⊙ Closed Loop Enabled

Frequency	Max Stim Current	ECAP Target Maximum	Measurement Type	ECAP Amplifier Gain
10Hz	30.0mA	200µV	Filter (-)	Low (±7.2mV)

ClearCAP™	Current Increment	ECAP Target Increment	Sampling Period	Processing Offset
Disabled **Enabled**	0.8mA	5µV	3662µV	122µs

Patient Sensitivity	Inter Stimulus Interval	ECAP Target Minimum	Sampling Delay	Filter Frequency
40µV/mA	30000	0µV	200µs	1214Hz

Stimset 1	Stimset 2	Stimset 3	Stimset 4.Empty
Pulse Width	Pulse Width	Pulse Width	Pulse Width
200µs	240µs	240µs	240µs
Interphase Gap	Interphase Gap	Interphase Gap	Interphase Gap
500µs	200µs	200µs	200µs
Stim Set Ratio	Stim Set Ratio	Stim Set Ratio	Stim Set Ratio
1	1	1	1
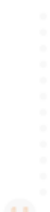
Program Legend

Anode	Cathode	Measurement	Reference
➕	➖	〰	⏺

Stimulator Information

Stimulator	#523 / Te: 4.0.11.0 / Th: 6.0.9.0
Clinical Interface	#042710793553
EPC Mode Change	Enabled
Log Settings	Normal, 6 Months

Lead Information

# of Leads	2
Type	Percutaneous 1x12
Implant Date	02 AUG 2021
Electrode Spacing	4mm
Electrode Length	3mm
Electrode Span	80mm

Programming parameter changed during programming session

- If no changes were made to a particular parameter during the programming session, the parameter will be listed as seen on the left-hand figure. The final setting will be centered in the appropriate colored font. Orange = Closed-loop Enabled or Blue = Closed-loop disabled.

- If a change was made to a particular parameter during the programming session (compared to programs on the stimulator on the first connection for that day), the original setting will be listed in black on the left and the entire parameter will be outlined in black.

Examples of Stim-Sets in RECAP Report

1. Stim-Set 1 – Enabled, electrode configuration changed during programming session. Small colored dots represent initial electrode configuration and large colored dots represent final electrode configuration
2. Stim-Set 2 – Disabled, empty since initial interrogation
3. Stim-Set 3 – Disabled, Stim-Set was erased during program session
4. Stim-Set 4 – Enabled, no changes made during program session
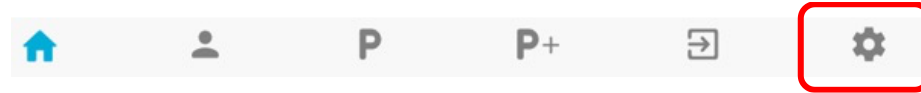
6.7 Settings Page

Touch the ⚙ to navigate to the *Settings Page*. On this page you will find the following information and buttons.

Application Version	CPA Firmware Version
Device ID	CI Serial Number
Language	English
Data Synchronization	Uploads files from the "SaludaData" folder on the CI to a centralized file server
CLS	External Closed-Loop Stimulator or Closed-Loop stimulator serial number, therapy and telemetry firmware versions
Log Setup	Set up therapy log settings: Size: Normal (1.5 MB) or Research (13 MB) Duration: 1 day to 1 year, Off
Software Reset button	Reset stimulator, clear Safe Mode errors, clear programs and reconnect
Factory Reset button	Restore devices to default factory settings. For use by Saluda Medical Field Clinical Engineer (FCE).
Enter Stock Mode button	Stop all CLS functions to conserve battery. Use the Charger to leave stock mode.
Exit CPA button	Exit the application.

6.7.1 Data Synchronization

6.7.1.1 *Data files*

All data downloaded from the stimulator and recorded during a programming session is saved to a clinical data log file (.log or .gz) on the CI, in a device folder, for later review. Folders are created and files are saved on the CI in the 'SaludaData' folder, per the following naming convention.

> This PC/Windows/ProgramData/ClarityData/SaludaData/<patient folder>/<visit folder>/
Where:

- An example of 'patient folder' is:
    20210721-2010-0089-8uc5-042120500000_SN0000   _
    Date of initial connection – unique identifier – CI serial number _ stimulator SN

- An example of 'visit folder' is: 2021-07-23.11-37-55.512
                              Visit Date . Time of initial connection

For more information on the data files and how to view them, refer to the Evoke SCS System RECAP™ Viewer User Manual.

6.7.1.2 *Data upload*

The Data Synchronization feature within the CPA uploads files from the "SaludaData" folder on the CI to a centralized file server. Data upload can occur while connected to a patient and won't affect standard CPA functionality.

6.7.1.3 *Starting the data upload*

If enabled, the CPA automatically scans and attempts to upload new data every 30 minutes as long as the CI is connected to the internet. If connected to a stimulator, it will not attempt to upload the session currently in progress.

To manually start the sync:

1. Ensure the CI is connected to the internet.
2. Go to the System Settings page ⚙.
3. Touch the Start Sync **Start Sync** button.
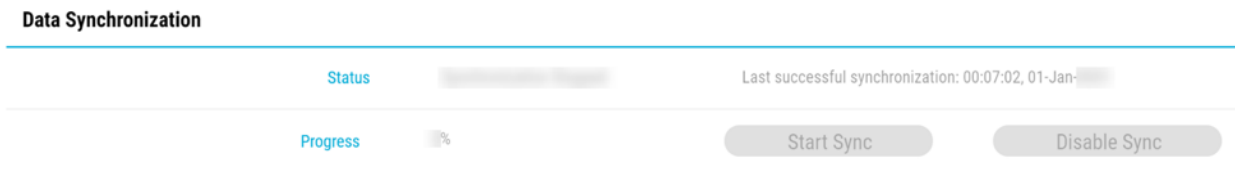
Figure 6.55: Layout of Data Synchronization section in System Settings page.

Button/Field	Description
Status	Can be any of the following: • **Synchronizing…** : Synchronization is in progress • **Connection Error**: No internet connection • **Invalid CI**: CI serial number is not approved • **Synchronizing Disabled**: Synchronization has been disabled • **Synchronizing Failed**: Synchronization failed to complete • **Synchronizing Complete**: Synchronization has completed successfully The Status also notes the date of last successful synchronization.
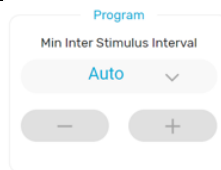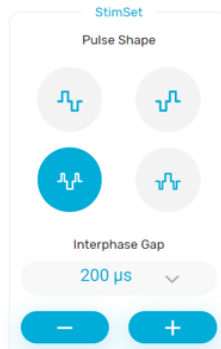
Progress	Indicates what percent of data has been checked and uploaded.
Start Sync button	Enables data upload to the server, running every 30 minutes. Will be available when not connected to a device and if synchronization is currently disabled. Will be disabled when you start synchronization. **Note:** You cannot manually enable synchronization while connected to a device (however, if it is already enabled it will upload all but the current session in the background).
Disable Sync button	Prevents data synchronization until it is re-enabled. Will be available if synchronization is currently enabled.

7. CPA – Settings guide

7.1 General CPA buttons and icons

⊕	Add Button (if standalone)	+	Increase Button
❗	Alert Icon – toggle over icon to see error details	˄	Increase Stimulation Button
☰	Clear Pain Drawing Button	▢	Load Button
˄	Collapse Button	▶❙	Next Button
—	Decrease Button	✎	Paint Button
˅	Decrease Stimulation Button	❙❙	Pause Button
🗑	Delete Button	✓	Save Button
↓	Download Button	💾	Save Program Button
✎	Edit Button	▶	Start button
◆	Erase Button	■	Stop Button
˅	Expand Button	STOP	Stop Stimulation Button
✕	Exit/Close Button	🔃	Sync Icon
		◐	Toggle Button

7.2 Coverage Settings

Basic	
Frequency (Hz) *	10 – 1500 Hz closed-loop disabled 10 – 250 Hz closed-loop enabled
Current Increment *	0.05 mA – 4.0 mA (depending on the electrode setup)
Pulse Width^	20 – 1000 µs

Advanced	
Min Inter-Stimulus Interval *	Interval of Stim-Set pulses Auto (minimum permitted ISI), 1400 – 50000 µs
Pulse Shape^	Biphasic - Positive first, Negative first Triphasic - Positive first, Negative first
Interphase Gap^	20 – 500 µs

Note: *Stim-Set Parameters*^ only apply to the selected Stim-Set. *Program Parameters* *
apply to all Stim-Sets. The available range of each setting is shown.
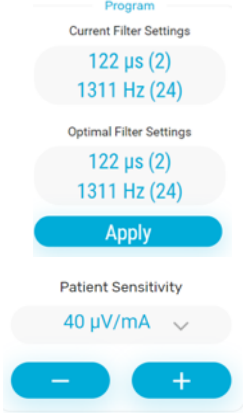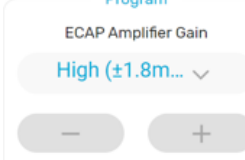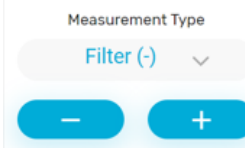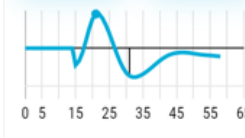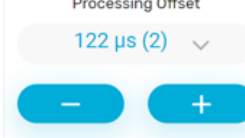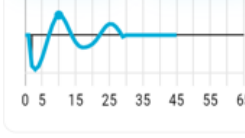
7.3 Acquisition Settings
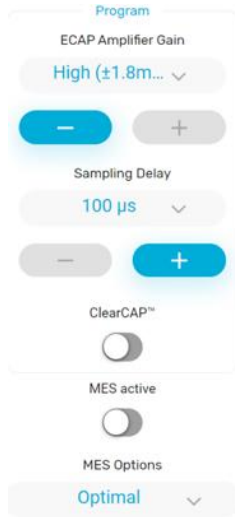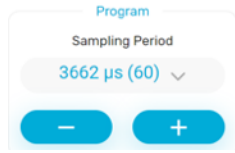
Basic	
Sampling Period*	122 – 10009 µs (2 – 164 samples)

Advanced	
ECAP Amplifier Gain*	Evoked Compound Action Potential telemetry amplifier gain setting.
	High (± 1.8 mV), Low (± 7.2 mV), Disabled
Sampling Delay*	100 – 1000 µs
ClearCAP*	Disable or Enable ClearCAP stimulation. Sets the Reference electrode as an input for ClearCAP.
MES Active^	*Disable* or *Enable* the measurement electrode scan for the duration of the programming session.
MES Options	Measurement electrode scan position configuration options.
	Optimal, Fixed Reference, Fixed Measurement, Fixed Distance.

Note: *Stim-Set Parameters*^ only apply to the selected Stim-Set. *Program Parameters* * apply to all Stim-Sets. The available range of each setting is shown.
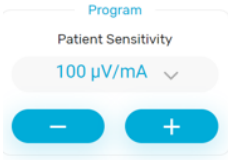
7.4 Filter Settings

Basic	
Optimal Filter Settings*	Press *Apply* to use recommended filter sample
Patient Sensitivity*	14 – 1000 µV/mA

Advanced	
ECAP Amplifier Gain*	Evoked Compound Action Potential Telemetry amplifier gain setting. High (± 1.8 mV), Low (± 7.2 mV), Disabled
Measurement Type *+	ECAP Sampling Disabled, Filter (+), Filter (-), Amplitude **Note:** For Raw data, Closed-loop is disabled and the settings for Processing Offset, Processing Period, Patient Sensitivity, and ECAP Target Increment are disabled.
Filter Frequency * (Filter +/- mode only)	496 – 1928 Hz (65 – 16 samples)
Filter Frequency plot (Filter +/- mode only)	ECAP amplitude vs. filter samples. Circle – recommended samples (peak of plot), Black line – samples used.
Processing Offset*	0 – 3662 µs (0 – 60 samples)
Processing Offset plot	ECAP amplitude vs. processing offset. Circle – recommended offset (peak of plot); Black line – offset used.

Note: *Stim-Set Parameters^* only apply to the selected Stim-Set. *Program Parameters* * apply to all Stim-Sets. The available range of each setting is shown.

+ For measurement, stimulation frequency must be 250 Hz or less for Raw Data and Amplitude, or 200 Hz or less for Filter (+/-) or if ClearCAP is enabled.
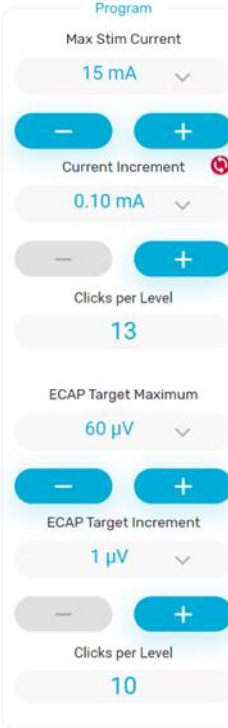
7.5 Evaluation Settings

Basic	
Patient Sensitivity*	14 – 1000 µV/mA

Note*: Program Parameters * apply to the selected program. The available range of each setting is shown.*

7.6 Program Settings

Program Settings apply to the selected program. The available range of each setting is shown.

Basic	
Maximum stimulation current	1 – 50 mA
Current Increment	0.05 mA – 4.0 mA (depending on the electrode setup and Max Stim Current)
Clicks per level (CL disabled)	Calculated number of clicks to change 1 light on the EPC to the next (depending on Max Stim Current and Current Increment)
ECAP Target Maximum	-900 – 10000 µV
ECAP Target increment	1 – 1000 µV
Clicks per level (CL enabled)	Calculated number of clicks to change 1 light on the EPC to the next (depending on ECAP Target Max and ECAP Target Increment)
Advanced	
Max Stimulation Voltage	7.5 – 15 V
ECAP Target Minimum	Minimum ECAP Target that can be set with the CPA or EPC (-1000 – 1000 µV)
ECAP Minimum	Minimum ECAP amplitude recorded by the stimulator (-1000 – 1000 µV)

	Link ECAP Minimums Toggle	Link 'ECAP Target Minimum' to the 'ECAP Minimum' value (enabled, default) or not linked (disabled).

	Charger Detection Toggle	Charger detection disables Closed-Loop enabled programs during CLS charging. When charging is started with stimulation on, if the mitigation is:
		
		• Enabled ⟷ , stimulation continues, with CL disabled.
		
		• Disabled ➡ STOP (default), then if:
		    ○ **CL enabled**: stimulation stops.
		    ○ **CL disabled**: Stimulation continues.
		
		 Note: This needs to be set for each program.

	EPC Therapy Toggle	When EPC Therapy is *Enabled* ⟷ , CL can be enabled/disabled from the EPC. When EPC Therapy is *Disabled* 🔒 (default)*,* CL cannot be enabled/disabled from the EPC. **Note:** This is a global setting and applies to all programs.
	Reset Program to Defaults	Reset the selected program to default parameters and delete all but the first Stim-Set (S1).

7.7 Program Management Settings
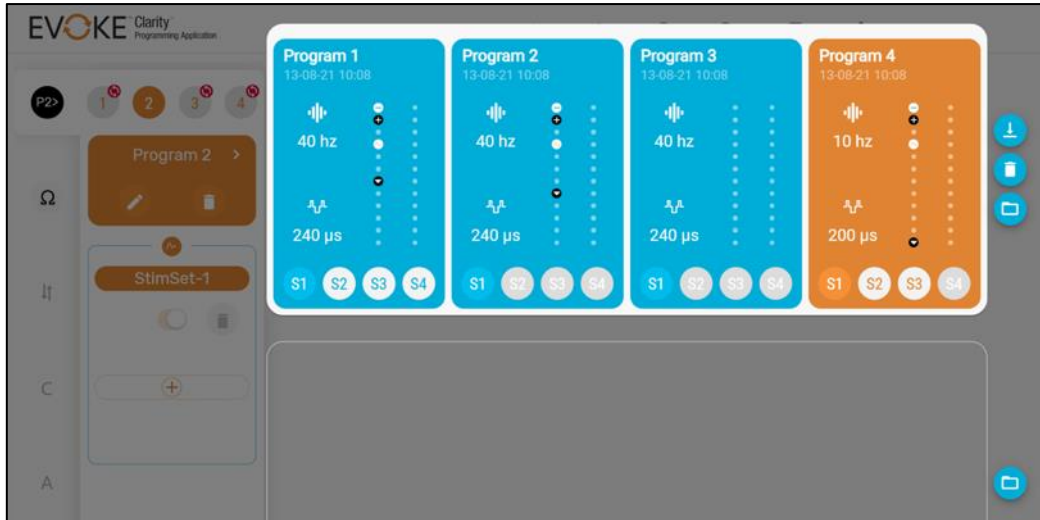
Figure 7.1: Program Management Settings.

Program Selection	Program, labeled Program 1 (P1), Program 2 (P2), Program 3 (P3), Program 4 (P4)	
Stim-Set Selection	Stim-Set slots, labeled Stim-Set-1 (S1), Stim-Set-2 (S2), Stim-Set-3 (S3) or Stim-Set-4 (S4). Dark grey circles with white font represent non-enabled Stim-Sets.	
Save Slot	Holds information from all 4 programs, as displayed on the CPA at the time they were saved. Automatically occurs upon connection to a stimulator	
Red Sync Icon	Represents an Unsynchronized program Located next to the number of the program Any program on the CPA that has not been run on the stimulator - New program - Modified program	

8. Behavior of the stimulator when alerts occur

Refer to Section 6.1.2 for how notifications are displayed on the CPA.

8.1 Out of Compliance

Out of Compliance (OOC) occurs when the voltage requirement exceeds the Maximum Stimulation Voltage (see Section 7.6). This may also occur with disconnected stimulation electrodes. When OOC is indicated, the patient may not increase intensity with the EPC, stimulation may stop, or the patient may feel a reduction in paresthesia intensity.

If OOC occurs with disconnected stimulation electrodes, or recording electrodes with ClearCAP enabled, then stimulation stops. If the electrodes are reconnected (e.g. their impedance reduces), stimulation may be restarted by the patient using the EPC and will ramp from 0 mA to the stimulation current set when the stimulator stopped. If the electrodes remain disconnected the stimulator will follow the behavior described in Section 11.3.

If OOC occurs when Closed-loop is enabled with electrodes connected, and the stimulator does not detect a problem with the ECAP measurement, then the stimulator will reduce the target value by half. If the stimulator detects a potential problem with the ECAP measurement, then stimulation stops. When stimulation is restarted by the patient, it will start at 0 mA of stimulation current, with Closed-loop disabled, and the patient will need to increase the stimulation intensity using the EPC. Closed-loop is automatically re-enabled, without interrupting stimulation, once the ECAP signal is detected. The system determines an ECAP has been detected when the ECAP amplitude reaches half the original target value.

If OOC occurs when Closed-loop is disabled with electrodes connected then stimulation will continue.

8.2 Reference Clock Error

A reference clock error is an indication that the timing used to generate the stimulation pulse is incorrect. When a reference clock error is indicated, Closed-loop is disabled until the error is cleared. Stimulation stops if the error is detected during multiple consecutive stimuli.

8.3 Electrode Disconnected

When the clinician or patient attempts to start stimulation, the stimulator checks the connection of each stimulation and recording electrode (if selected). If one or more stimulation electrodes are disconnected, then stimulation will not start. If one or more recording electrodes are disconnected, then stimulation will start with Closed-loop disabled.

8.4 Current at Maximum

If the stimulation current is at its maximum setting when Closed-loop is enabled, stimulation may stop, the patient may feel a reduction in paresthesia intensity, or Closed-loop may be disabled. If

recording electrodes are disconnected, then stimulation stops. When Closed-loop is enabled, if the stimulator detects a potential problem with the ECAP measurement, then stimulation stops, and Closed-loop is disabled until the ECAP measurement returns, as described in Section 8.3.

If the stimulator does not detect a problem with the ECAP measurement when Closed-loop is enabled, then the stimulator will reduce the target value by half. If the stimulator detects a potential problem with the ECAP measurement, then stimulation stops. When stimulation is restarted, it will start at 0 mA of stimulation current, with Closed-loop disabled, and the patient will need to increase the stimulation intensity using the EPC. Closed-loop is automatically re-enabled, without interrupting stimulation, once the ECAP signal is detected. The system determines an ECAP has been detected when the ECAP amplitude reaches half the original target value.

8.5 Clipping

For each stimulus, the stimulator checks the ECAP signal is within the ECAP amplifier gain limits. If the ECAP signal is outside these limits, or clipping, the stimulator checks the connection of each recording electrode. Stimulation may stop, the patient may feel a reduction in paresthesia intensity, or Closed-loop will be disabled until the clipping alert is cleared.

If Closed-loop is enabled and clipping occurs with disconnected recording electrodes, then stimulation stops. If the recording electrodes are reconnected, stimulation may be restarted by the patient using the EPC and will ramp to the target level set when the stimulator stopped. If the recording electrode remains disconnected the stimulator will follow the behavior described in Section 11.3.

If Closed-loop is enabled and clipping occurs with the recording electrodes connected, the stimulator will set the ECAP amplifier gain to Low and stimulation will continue. If clipping continues and the gain is already Low, the stimulator will reduce the target value by half and stop stimulation. When stimulation is restarted, it will start at 0 mA of stimulation current, with Closed-loop disabled, and the patient will need to increase the stimulation intensity using the EPC. Closed-loop is automatically re-enabled, without interrupting stimulation, once the ECAP signal is detected. The system determines an ECAP has been detected when the ECAP amplitude reaches half the original target value.

If Closed-loop is disabled and clipping occurs with disconnected recording electrodes while ClearCAP is enabled, then stimulation stops. If the recording electrodes are reconnected, stimulation may be restarted by the patient using the EPC and will ramp to the stimulation current level set when the stimulator stopped. If the recording electrode remains disconnected the stimulator will follow the behavior described in Section 11.3.

If Closed-loop is disabled and clipping occurs with disconnected recording electrodes while ClearCAP is disabled, then stimulation continues.

If Closed-loop is disabled and clipping occurs with the recording electrodes connected, the stimulator will set the ECAP amplifier gain to Low and stimulation continues.

9. Evoke Charger

Refer to the Evoke SCS System User Manual for full details on use of the Evoke Charger to charge the CLS.

The stimulator battery status is displayed in the status bar (see Section 6.2.3). If the stimulator is being charged when connected to the CPA, an indication is displayed on the stimulator battery icon.

9.1 Stimulation during charging

9.1.1 Closed-loop disabled

When closed-loop is disabled, charging does not affect stimulation.

> **Note:** During charging, ECAP measurements may be distorted by the charging field.

9.1.2 Closed-loop enabled

When closed-loop is enabled:

1. Stimulation should be stopped before charging is started. Stimulation can be stopped using the CPA or the EPC (see Evoke SCS System User Manual).
2. During charging the CLS automatically disables closed-loop stimulation.
3. After charging has started, stimulation may be turned on, but closed-loop will remain disabled. Stimulation will restart at the current level saved when stimulation was stopped.
4. If charging starts while stimulation is on, the CLS can be set using CPA to respond in one of two ways (see Section 7.6):

    (Default setting)

   a. Stimulation will **automatically stop** when charging is detected. After charging has started, stimulation may be turned on, but closed-loop will remain disabled. Stimulation current will be set to 0 mA and the patient can increase it with the EPC.

   b. Stimulation continues with **closed-loop disabled** when charging is detected, and the stimulation current is set to the minimum from the previous 10 seconds.

5. After charging has finished, the CLS will wait 25.25 seconds and then automatically enable Closed-loop. If stimulation is on, the ECAP amplitude target is set to the smaller of: the target before charging started; or the average ECAP amplitude from the 5 seconds before Closed-loop is automatically enabled.

⚠ **Caution**: Refer to the Evoke SCS System Surgical Guide for precautions when operating equipment. During charging, closed-loop is disabled, so patients should turn stimulation off if charging while driving or operating equipment.

Note: When the CLS automatically enables or disables closed-loop stimulation, the patient may feel changes in paresthesia intensity.

Note: During charging, ECAP measurements may be distorted by the charging field.

10. Patient education and ID card

Educate the patient on the use of their EPC and Charger (if applicable) using the Evoke SCS System User Manual.

All patients should be supplied with a Patient ID card for the clinician to complete.

1. Give the completed Patient ID card to the patient so that they can use it to show other medical practitioners or security personnel that they have an active implanted medical device.

2. Educate the patient to show the Patient ID card to healthcare professionals before undergoing any medical procedure.

3. The Evoke System has not been tested for MRI compatibility and is MR unsafe. The Patient ID card indicates that the patient **must not** undergo an MRI scan with the Evoke System implanted.

11. Maintenance of the Evoke CI and Evoke CST

11.1 Maintenance of the Evoke CI

Maintenance and cleaning of the Clinical Interface should be carried out according to instructions in the device manual accompanying the CI tablet.

11.2 Updating the Evoke CI Software

The CI contains software that automatically checks if there are any updates that can be downloaded and applied to the CI. The CI must be connected to the internet for this check and update to be completed.

When the software detects that an update is required it will show the following message:
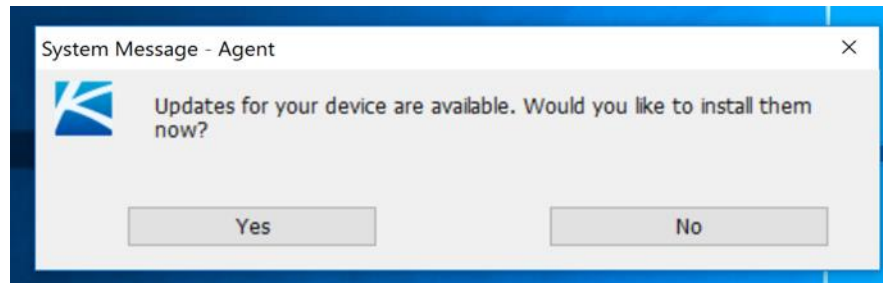
Figure 11.1: Prompt message for software update.

Touch "Yes" to download and apply the updates now, or "No" if you wish to update later.

> **Note:** The update should be applied as soon as possible, but if there is not sufficient time the software will continue to popup reminders until the update is applied.

The update process will take several minutes during which you will be unable to use the programs. You will receive a message once the update for each program is complete.
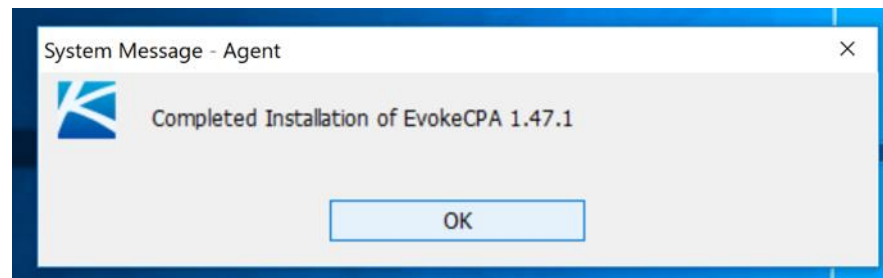
Figure 11.2: Example program update message.

You will receive another message once the full update process has been completed and the CI is ready for use.
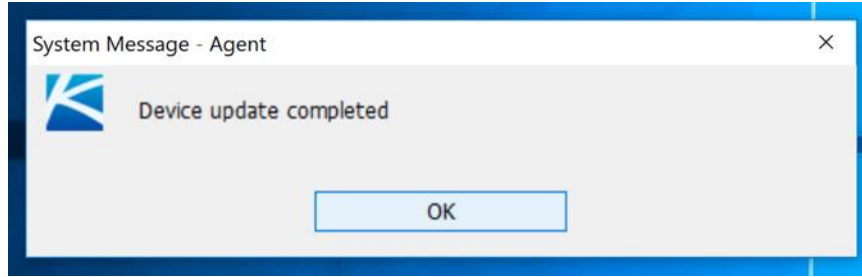
Figure 11.3: Device update completion message.

⚠ **Caution:** It is important to apply the updates as soon as possible as they may contain important safety or security improvements.

11.3 Maintenance of the Evoke CST

The CST is not expected to be in direct contact with patients but should still be periodically cleaned. The CST can be cleaned with a soft cloth dampened with a mild disinfectant or alcohol.
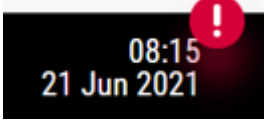
Refer to the Evoke SCS System User Manual for advice on the maintenance of additional components of the Evoke SCS System.

11.4 Disposal of devices

DO NOT dispose of the CI or the CST in municipal waste facilities. Please return any items to Saluda Medical via your Saluda Medical representative for proper disposal.

12. Troubleshooting

Table 12.1: Troubleshooting.

Issue	Likely Explanation(s)	Corrective Action(s)
CI will not turn on.	CI battery may need recharging.	Attach power supply to CI and plug into power outlet.
CI does not respond or is slow to respond	CI operating system may not be functioning correctly	Restart the CI by shutting down or restarting. If the CI does not respond, shut down the CI by pressing the power button for 10 seconds. Then release the power button and press it again to restart the CI.
Programming software ('Clarity') icon is not visible.	Icon may have been moved or deleted.	Using the CI search function, locate and select the 'Clarity'. The program should start. If this procedure fails, please call your Saluda Representative.
Touching the programming software ('Evoke CPA') icon does not start the software.	The shortcut link has been broken or target file moved.	Using the CI search function, locate and select 'Clarity'. The program should start. If this procedure fails, please call your Saluda Representative.
Stimulator cannot be found by CPA.	Stimulator battery may need recharging or is in Stock Mode.	Apply the Charger to the stimulator, charge if required.
CST to stimulator connection fails due to time out.	CST may be too far from stimulator.	Move CST closer to stimulator. Ensure no EMI from other devices. Restart the CPA and/or the CI if issues persist.
Exclamation mark appears over CI time. 08:15 21 Jun 2021	Stimulator time is not synchronized.	Synchronize stimulator time (Section 6.2.2), confirm the exclamation mark disappears. **Note:** Stimulation must be off.
Unable to start stimulation on CPA.	Stimulation may already be running and the CPA is out of sync.	Press the 'Stop' button again to ensure stimulation is off.

Issue	Likely Explanation(s)	Corrective Action(s)
	Minimum electrode configuration has not been programmed.	Configure required electrodes (Section 6.4).
	Stimulation parameters may exceed allowable limits.	Check pulse width, frequency, current increment, maximum current, interphase gap (IPG), and sampling period and ensure the combination in use is within system limits.
Patient cannot feel increasing stimulation	Stimulation may not be at Threshold yet.	Continue to increase stimulation until patient reports feeling stimulation.
	Communication may be disrupted - Active Current level not changing while Current Setpoint continues to increase (Section 6.4.4.1).	Stop stimulation. Ensure there is good communication (Section 6.1.2.5), move CST closer to stimulator. Ensure no EMI from other devices. Restart the CPA and/or the CI if issues persist.
Cannot enable Closed-Loop on CPA.	Recording electrodes have not been configured or are disconnected.	Check electrode impedances (Section 6.4.1). Configure recording electrodes (Section 6.4.4.2).
	Sampling period may be too small.	Increase sampling period/number of samples ('+' button).
Parameter or control button greyed-out.	Certain rules may not be met for the current program configuration.	Check for notification icons on certain buttons and the information in the *Notes* (Section 6.1.2).
	Parameter may not be adjustable in the current mode.	Turn stimulation off and attempt to adjust the parameter to the desired level.
No data in rolling plot or rolling plot lacks data points and appears 'lumpy' or 'spiky'.	System may be busy or MES may be enabled.	Ensure MES is disabled. Wait for condition to clear or re-start software. Close other applications that are running (e.g. RECAP Viewer).
	Communication may be disrupted.	Move CST closer to device. Ensure no EMI from other devices (e.g. phone).

Issue	Likely Explanation(s)	Corrective Action(s)
CPA freezes or has very slow response.	Other applications open.	Restart the CPA. Close other applications that are running. Ensure the CST is close to the stimulator. Ensure no EMI from other devices (e.g. phone).
Patient cannot raise stimulation to their desired level using the EPC.	Maximum Stimulation Current may be too low.	Raise Max Stim Current (Section 7.6).
	ECAP Target Maximum may be too low.	Raise ECAP Target Maximum (Section 7.6).
Patient or Programming clinician cannot raise stimulation above zero with the EPC.	Stimulator may be in *Safe Mode*.	Perform 'Soft Reset' (Section 6.7).
	Stimulator may be reaching voltage compliance limit (Section 8.1). Stimulator may have Electrode Disconnected error (Section 8.3).	Perform an impedance check to ensure all connections are ok (Section 6.4.1). **If an eCLS:** Check intraoperative cable, lead adapter and eCLS connections.
	EPC may not be communicating with the stimulator.	Ensure you have disconnected with the CPA. Check that the audio indicators are enabled and if 3 beeps are heard bring the EPC closer to the stimulator and try again.
Patient reports high variability in stimulation.	Stimulator needs device check and possible reprogramming. Interrogate with the CI/CPA to confirm CL is enabled, noting any error messages.	Reprogram the stimulator and test new settings (Section 5). Check the Patient Sensitivity setting, remeasure the activation plot and ensure the ECAP signal is acceptable.
	Patient is moving while charging the CLS or eCLS	The CLS will only operate with CL disabled while it is being charged. Stimulation should be turned off or the patient should not move too much if the stimulation strength variation is unpleasant.

Issue	Likely Explanation(s)	Corrective Action(s)
Contact Clinician Indicator Light is on either Charger or EPC.	Stimulator is in *Safe Mode*. 	Note down the error on the screen; **Note:** You can take a screenshot with the CI by pressing and holding Fn+Windows+Spacebar. Perform 'Soft Reset' (Section 6.7).
CST not detected.	CST is not plugged in.	Plug CST into USB port and restart the CPA.
ClearCAP disabled error	Recording or reference electrode is disconnected.	Check electrode connectivity with an impedance check (Section 6.4.1).
Clipping causes stimulation to stop.	Recording or reference electrode is disconnected.	Check electrode connectivity with an impedance check (Section 6.4.1).
	Input to amplifier is too large.	Switch to low gain mode.
		Check the impedances and the connections to the stimulator if using an eCLS.
	Charging has been started while the stimulator is operating with CL enabled.	Restart stimulation, check the charger mitigation feature setting (Section 7.6).
Current at Maximum.	Maximum current limit may be too low.	If the patient does not report any surges in stimulation and only cutting out, increase the Max Stim Current (Section 7.6).
	High artifact.	Check the activation plot, if it is not the correct shape try changing recording or reference electrodes. Increase pulse width to reduce current requirement. Enable ClearCAP (Section 7.3)
	Electrode disconnection.	Check the impedances (Section 6.4.1) or refer to 'Electrode Disconnected' (Section 8.3).
	CL stimulation is on when charging is started.	Turn off the Charger and see if the problem persists; check the charger mitigation feature setting (Section 7.6).

Issue	Likely Explanation(s)	Corrective Action(s)
Out of Compliance.	Voltage limit may be too low.	Confirm voltage limit is set to 15 V (maximum), see Section 7.6.
	Required voltage exceeds system limits.	Increase pulse width to reduce current requirement.
	Electrode impedance may be too high.	Check impedances and, if high, select a different stimulating electrode if possible (Section 6.4.1). Add more return electrodes.
	CL stimulation is not working as intended.	Check the activation plot, it should be linear and increasing. If it is not, try changing recording or reference electrodes.
Download logs failure.	Download of log file has failed.	Attempt to re-download the logs (Section 6.2.2).
	Ensure 'Factory Reset' has been completed after a firmware upgrade	Perform a 'Factory Reset' (Section 6.7) if you have just completed a firmware upgrade.
Electrode disconnected.	Electrode may be broken, or in highly resistive tissue.	Reprogram using a different electrode. If immediately post-surgery, situation may resolve after 24-48 hours.
	Electrode may be disconnected from intraoperative cable, lead adapter or stimulator.	Remove the proximal connector end from the intraoperative cable, lead adapter (or CLS if permanent implant procedure), clean the contacts and re-insert.
Data won't synchronize/upload and/or reports will not email	Invalid CI	Contact your Saluda Representative to ensure the CI is on the approved list.
	Connection Error	Ensure you have an internet connection.
	Consent is not set appropriately.	Data will not be uploaded and Reports cannot be emailed if the consent has not been set appropriately for the region (see Section 6.3.1).

13. Package contents

Table 13.1: Package contents.

Package	Package Contents
Evoke Clinical Interface (CI) (Ref No.: 3024)	1 x Tablet Computer 1 x Tablet Keyboard 1 x Power Adapter
Evoke Clinical System Transceiver (CST) (Ref No.: 3004)	1 x Clinical System Transceiver (CST)

14. Technical Specifications

14.1 Device Specifications

Refer to the Evoke SCS System User Manual and Evoke SCS System Surgical Guide for device specifications for additional components of the Evoke SCS System.

14.1.1 Evoke CI Tablet specifications

The CI tablet computer has minimum hardware specifications as follows:

Table 14.1: Evoke CI tablet minimum hardware specifications.

RAM	8 GB
Storage	128 GB
USB port	USB 2.0
Display type	Touchscreen
Display size	12.3 inches
WiFi	802.11 a/b/g/n/ac compatible
Camera resolution	5 MP

14.1.2 Evoke CST specifications

Table 14.2: Evoke CST specifications.

Materials	Top and bottom cases	ABS Plastic
	Intermediate Ring	TPE
	Cable Sheath	PVC
Dimensions	CST	85 x 55 x 16 mm (3.35 x 2.65 x 0.65 in)
	Cable	1 m (3 ft 3.6 in)
Weight	46 g (1.6 oz)	
Power Source	USB port of Evoke Clinical Interface (CI), +5 VDC, 0.5A	
Communications Link	MICS band (402–405 MHz) half-duplex radio frequency communication. CST – Master, CLS/eCLS - Slave	
Radio frequency communication	MICS band	402-405 MHz
	8 channels*	Centre frequency (MHz): 402.45, 402.75, 403.05, 403.35, 403.65, 403.95, 404.25, 404.55
	Transmit/Receive Channel Bandwidth	300 kHz
	Modulation type	Frequency Shift Keying (2FSK)
	Raw Data rate	200kbs
	Antenna type	Internal PCB mounted antenna

	Antenna Gain	-8.7dB (manufacturer's data)	
	Range	1.0 m (3.3 ft.)	
	Effective Isotropic Radiated Power (EIRP)	25 μW (-16.02 dBm) maximum	
	FCC ID	2AYGR-3004	

*Channel selection is based on Clear Channel Assessment (CCA) protocol whereby CST, being a Communication Link Master, selects the channel with the lowest interference level before communication session begins.

Ingress Protection	IP54 Rating for protection against failure from limited dust ingress, and protection against failure from splashing water.		
IEC 60601-1 / EN 60601-1 Classification	Class II Medical Electrical Equipment Continuous Operation Portable Type BF applied part		
Storage & Transportation Conditions	Temperature: Humidity: Pressure:	Min: -20 °C (-4 °F) Min: 0% RH 70 kPa (0.69 atm)	Max: 60 °C (140 °F) Max: 90% RH Max: 106 kPa (1.05 atm)
Operating Conditions	Temperature: Humidity: Pressure:	Min: 5 °C (41 °F) Min: 15% RH 70 kPa (0.69 atm)	Max: 40 °C (104 °F) Max: 90% RH Max: 106 kPa (1.05 atm)

14.2 Wireless Communication

14.2.1 Quality of Service & Wireless Coexistence

The Evoke SCS System employs a wireless communication link operating in the 402-405 MHz MICS frequency band. This band is designated for implantable medical devices and enables communication between the CLS/eCLS and the CST or EPC.

At the beginning of each communication session, the CST or EPC automatically scans 8 channels in the frequency band and selects the least congested channel for communication. All communication is error checked and is retried automatically. The user is notified if the wireless communication link fails to connect.

The communication range between the CST/EPC and the CLS/eCLS is typically 1 meter (3.3 feet). If you experience issues with the wireless communication between the CST/EPC and CLS/eCLS, try the following:

- Decrease the distance between the devices.
- Move the devices away from other devices that may be causing interference (see Section 14.3).
- Restart the CPA, wait a few minutes and try connecting again.
- Do not operate other wireless devices, such as a mobile phone, tablet or laptop, at the same time.

14.2.2 Wireless Security

The Evoke SCS System has a communication range of 1 meter (3.3 feet). To enable the CST/EPC to communicate with an eCLS or CLS, it must first be paired with that stimulator. The CST/EPC may communicate with only one CLS or eCLS at a time. The stimulator will not respond to any communication that does not come from a paired device. Additional mechanisms are in place to safeguard the integrity of the communication. There are no security settings that require input or control by the user.

14.3 Electromagnetic Interference

The following tables indicate the electromagnetic environment in which the Evoke SCS System is intended to operate. This is to ensure compliance with international standards for the electromagnetic interference (EMI) produced by the Evoke SCS System, or the susceptibility of the Evoke SCS System to EMI. For more information on this section please contact a Saluda Representative.

⚠ **Caution:** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

14.3.1 Guidance and Manufacturer's Declarations

Table 14.3: Electromagnetic emissions.

The Evoke SCS System is intended for use in the electromagnetic environment specified below. The patient, doctor or any other user of the Evoke SCS System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
Radiated disturbance, 30 MHz - 6000 MHz CISPR 11 (EN 55011)	Group 1, Class B	Evoke SCS System is unlikely to produce electromagnetic interference with nearby electronic equipment.
Conducted Emissions 0.15 MHz -30 MHz CISPR 11 (EN 55011)	Class B	Evoke SCS System is suitable for use in all establishments, including domestic establishments 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	Not applicable for the battery powered devices or device consuming less than 75 W from mains power outlet (Charger with power adapter)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable for the battery powered devices. Charger with power adapter complies with requirements of the standard	

Table 14.4: Electromagnetic immunity – electrostatic discharge and mains power.

The Evoke SCS System is intended for use in the electromagnetic environment specified below. The patient, doctor or any other user of the Evoke SCS System should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 gaseous discharge at 100 kHz repetition frequency	± 2 kV @100 kHz repetition frequency for power supply lines to Charger power adapter	Mains power quality should be that of a typical household, commercial or hospital environment. If the user of the Evoke Charger power adapter requires continued operation during mains power interruptions, it is recommended that the Evoke Charger power adapter be powered from an uninterruptible power supply or a battery.
Surge Immunity IEC 61000-4-5	± 0.5 kV, ± 1 kV	± 0.5 kV, ± 1 kV power supply line to Charger power adapter	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips: 0% residual voltage for 0.5 cycle at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °, 315 °; 0 % residual voltage; 1 cycle, and 70% residual voltage; 25/30 cycles Single phase: at 0° Voltage Interruptions: 0% residual voltage; 250/300 cycles	Voltage Dips: 0% residual voltage for 0.5 cycle at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 °, 315 °; 0% residual voltage for 1 cycle at 0 °; 70% residual voltage for 25 cycles at 0 °; Voltage Interruptions: 0% residual voltage for 250 cycles at 0 °; Interval between Events – min. 10 s; Test cycle – 3 times;	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical household, commercial or hospital environment.

Table 14.5: Electromagnetic immunity – radio frequency.

The Evoke SCS System is intended for use in the electromagnetic environment specified below. The patient, doctor or any other user of the Evoke SCS System should ensure that it is used in such an environment.

⚠️**Caution:** Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer to any part of the Evoke SCS System, including the cable, than the recommended separation distance stated below (0.3 m, 12 inches). Otherwise, degradation of the performance of this equipment could result.

⚠️**Caution:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz; 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz	The Charger power adaptor functioned correctly during the test. Not applicable for a battery-powered device.	The separation distance between an interfering RF transmitter and any Evoke stimulator should be greater than 0.3 m and the maximum power from the RF transmitter should not exceed 2 W or 28 V/m at a distance of 0.3 m.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m for professional healthcare facility environment or 10 V/m for home healthcare environment	
Proximity fields from RF wireless communications equipment	Up to 28 V/m at 0.3 m at specified frequencies (refer Table 9, IEC 60601-1-2)	Tested at up to 28 V/m, devices continued to function during test.	

14.4 Federal Communications Commission (FCC)

14.4.1 Interference Statement for CLS, eCLS, CST, EPC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment 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 in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

⚠️FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The devices in the Evoke System may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

For MedRadio transmitters operating in the 401-406 MHz band, the following statement applies:

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.

14.4.2 Charger

This device complies with Part 18 of the FCC Rules.

14.4.3 Radiation Exposure Statement

The products comply with the FCC portable RF exposure limit set forth for an uncontrolled environment and are safe for intended operation as described in this manual.

15. Glossary of terms

Table 15.1: Glossary.

Term	Definition
Accessory Belt	An elastic belt with a pouch to hold an eCLS or a Charger coil.
Activation (spinal cord activation)	The population of spinal cord nerve fibers, in which ECAPs are initiated in response to stimulation. Activation may be estimated by ECAP amplitude.
Activation Plot	A plot of activation as a function of stimulus current for one or more postures.
Activation Plot Levels	Defined activation levels (listed below), reported in ECAP amplitude and stimulation current, collected when measuring the activation plot.

Level	Description
Threshold (T)	The activation level at either: • ECAP threshold: when ECAPs are first detectable. • Patient perception threshold: when the patient first feels a change in sensation (e.g. paresthesia, pain relief).
Comfort	The activation level at which the patient reports a preferred comfortable sensation:
(C-)	• When increasing stimulation from threshold.
(C+)	• When decreasing stimulation from maximum.
Maximum (M)	The activation level the patient could tolerate for no more than approximately one minute.

Term	Definition
Anode	A stimulation electrode denoted by the **+** symbol, also referred to as the return electrode. The pulse shape at an anode is the inverse of what's shown for Pulse Shape.
Artifact	A signal resulting from a stimulus that is not related to neural activity, but interferes with measurement of an ECAP.
Artifact Estimate	An estimate of the artifact that is extracted from the ECAP signal.

Term	Definition
Biphasic Pulse	A stimulation pulse consisting of two phases: a positive phase and a negative phase. The pulses are constant current, charge-balanced, rectangular, symmetrical, and the phases are separated by a short programmable interphase gap.
Cathode	A stimulation electrode denoted by the ‒ symbol, also referred to as the stimulating electrode. This is the electrode type that the Pulse Shape refers to. The percentage of current through this electrode can be configured when there is more than one of them.
Charger	The device that charges the battery in the CLS.
Charger Coil	A circular paddle connected to the Charger that is held over the CLS to charge the CLS battery.
Charger Power Adapter	The power supply adapter for the CLS Charger.
Chronaxie	The minimum pulse width needed for neural activation at twice the rheobase current. Chronaxie is also known as the excitability constant or membrane time constant.
ClearCAP	A feature that can be enabled to modify the circuitry behind the reference electrode to help with artifact mitigation.
Clinical Interface (CI)	A computer loaded with the CPA software, which is used to program the CLS/eCLS.
Clinical System Transceiver (CST)	The device that connects to the CI via USB, and exchanges information between the CI and the CLS/eCLS.
RECAP Viewer	A software application on the CI that can be used to analyze data generated by the Evoke System during a programming session or data downloaded from a stimulator.
Clinical Programming Application (CPA)	A computer program user interface that provides the functionalities required to program and analyze the performance of the CLS/eCLS.
Closed-Loop (CL) Stimulation	Stimulation that is automatically adjusted in response to a measured ECAP amplitude to maintain a target activation level. This is also known as ECAP-controlled closed-loop stimulation or (in the Evoke Clarity Programming Application) 'feedback enabled' stimulation.

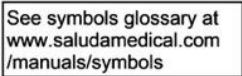| Term	Definition
Closed-Loop Stimulator (CLS)	An implantable pulse generator capable of ECAP-controlled closed-loop stimulation.
Conduction Velocity (CV)	The speed at which an ECAP propagates along the neural pathway, measured in meters per second (m/s).
Constant Current Stimulation	Stimulation using a current source in which output current is controlled at a fixed level across each pulse.
Dorsal Column	The dorsal region of the spinal cord, which is the primary target of SCS. The dorsal column is made up of Aβ fibers. When they're activated by stimulation, action potentials propagate up and down the Aβ fibers in the dorsal column.
Dorsal Root	The branch of a spinal nerve containing sensory or afferent nerve fibers that travel to the dorsal root ganglion and then enter the spinal cord, travelling to spinal cord tracts such as the dorsal column, or to synapse in the dorsal horn.
Electrode	An electrical contact that may be employed to deliver stimulation current or measure neural responses.
ECAP Amplifier	The measurement amplifier in the CLS/eCLS used to measure ECAPs.
Evoke Patient Controller (EPC)	A remote control that allows the patient to adjust the stimulation output from the CLS/eCLS.
Evoked Compound Action Potential (ECAP)	The measured sum of electrical signals from multiple nerve fibers elicited by an electrical stimulus.
ECAP estimate	An estimate of the ECAP without artifact that is extracted from the ECAP signal.
External Closed-Loop Simulator (eCLS)	A non-implantable pulse generator capable of ECAP-controlled closed-loop stimulation.
Feedback Variable (FBV)	The measured parameter of spinal cord activation used in a closed-loop SCS system. In the Evoke System, the parameter used for FBV is ECAP amplitude.
Histogram	A graphical representation of the distribution of data from the therapy logs (including current, ECAP amplitude and target, over a period of time).
Interphase Gap (IPG)	The delay between phases of a stimulation pulse.

Term	Definition
Intraoperative Cable	Sterilized cable which enables the connection between leads/lead extensions and the eCLS.
Late Response	A neural response resulting from dorsal root activation. Late responses occur after the ECAP and do not propagate along the spinal cord.
Lead	Insulated cable with a number of exposed electrodes at the distal end used in neurostimulation therapy.
Lead Adapter	An adapter that enables the connection between leads/lead extensions and the eCLS.
Lead Extension	Insulated cable that connects to the proximal end of a lead and in turn connects to either a CLS or lead adapter.
Lead Offset	The vertical alignment of two implanted leads, which may be estimated using the lead offset measurement feature.
Log Files:	Data saved on the stimulator during patient use that can be downloaded by the CPA for analysis with the RECAP Viewer.
Usage Log	A time-stamped record of patient and clinician interactions with the stimulator, and the stimulator status.
Error Log	A time-stamped record of alert and error events associated with stimulation.
Therapy Log	A record of current, ECAP amplitude, and target for each stimulation pulse, accumulated and compressed over fixed time-periods (e.g. every 4 hours), and used to generate histograms.
Maximum Charge Factor	A setting used during the automated chronaxie and rheobase test to determine the maximum stimulation current to be used for each pulse width. The factor is the ratio (0 to 1) between the patient reported maximum current at the initial test pulse width and the equivalent current at infinite pulse width.
Measurement Electrode Scan (MES)	A display feature that can be enabled to allow signals from multiple combinations of measurement electrodes to be displayed simultaneously.

Term	Definition
Measurement Electrodes	Electrodes use in the measurement of an ECAP signal. Comprises the recording electrode and the reference electrode. The measured signal is the difference between what's measured on these two electrodes. "Measurement Electrode" (singular) is sometimes used to refer to just the recording electrode. *See also Recording Electrode and Reference Electrode.*
Neural Response Profile (NRP)	A set of objective measures characterizing a patient's response to spinal cord stimulation.
Open-Loop Stimulation	Stimulation delivered when closed-loop is disabled. The system delivers a fixed-output of stimulation current when closed-loop stimulation is disabled. In the Evoke Clarity Programming Application, this is also known as 'feedback disabled' stimulation.
Paresthesia	Sensation felt by the patient as a result of activation of Aβ fibers by the stimulation pulses.
Patient Sensitivity	A patient dependent setting that is prescribed by the clinician to optimize closed-loop stimulation.
Program	The complete set of parameters describing stimulation, recording, measurement and feedback. A program may contain up to 4 Stim-Sets.
Recording Electrode	One of the electrodes used in the differential measurement of an ECAP signal, also referred to as R+. This is typically the one placed closest to the stimulation electrodes. *See also Measurement Electrode.*
Reference Electrode	One of the electrodes used in the differential measurement of an ECAP signal, also referred to as R-. This is typically the one placed furthest from the stimulation electrodes. *See also Measurement Electrode.*
Return Electrode	*See Anode.*
Rheobase	The minimum stimulus current needed for neural activation at an infinitely long pulse width.

Term	Definition
Sensitivity	The slope of the activation plot above ECAP threshold measured by the CPA. Sensitivity is a measurement of the sensitivity of the neural response to stimulation current for a given posture and it is used as a guide for the patient sensitivity setting in closed-loop stimulation.
Spinal Cord Stimulation (SCS)	A treatment for chronic pain utilizing pulsed electrical signals delivered to the spinal cord.
Stim-Set	See Stimulation Set
Stimulation	The application of electrical current through electrodes.
Stimulation Electrode	Electrodes use in the delivery of a stimulation pulse. Comprises the cathode(s) and the anode(s).
Stimulating Electrode	*See Cathode.*
Stimulation Set	A set of stimulation parameters designed to target a particular area of the patient's pain. Also referred to as StimSet (in this manual and in the CPA).
Strength Duration Curve	A plot of the threshold current versus pulse width. The strength duration curve represents the excitability of the axons stimulated, or more specifically the excitability of the nodal membranes. It is described by two parameters, rheobase and chronaxie.
Target	The ECAP amplitude that closed-loop stimulation maintains by automatically adjusting stimulation current. The target is set by the clinician and may adjusted by the patient using the EPC.
Therapeutic Window	The therapeutic range of activation, defined by the ECAP amplitudes between threshold and maximum. Therapeutic window represents the range within which dorsal column fiber recruitment is occurring without uncomfortable side effects.
Triphasic Pulse	A stimulation pulse consisting of three phases of alternating polarity. The pulses are constant current, charge-balanced, rectangular, and the phases are separated by a short programmable interphase gap.

16. Symbols

Table 16.1: Symbols.

Symbol	Definition
www.saludamedical.com/manuals	Follow the instructions for use at this website: www.saludamedical.com/manuals
	Follow the instructions for use
www.saludamedical.com/manuals	Follow the instructions for use at this website: www.saludamedical.com/manuals
See symbols glossary at www.saludamedical.com/manuals/symbols	Symbols Glossary can be found on this website: www.saludamedical.com/manuals/symbols
Caution	Caution
REF	Catalogue number
SN	Serial number
LOT	Lot number
UDI	Unique Device Identifier
YYYY-MM-DD	Use by date (YYYY = year, MM = month, DD = day)
	Temperature limitation (°F and °C)
	Manufacturer
YYYY-MM-DD	Date of manufacture (YYYY = year, MM = month, DD = day)
	Do not dispose of this product in the unsorted municipal waste stream – return to Saluda Medical for disposal
	Type BF applied part
	Non-ionizing electromagnetic radiation

Symbol	Definition
	Do not use if package is damaged
	MR Unsafe. Not safe to use with MR imaging
Qty	Contents
	Class II Medical Electrical Equipment
	Do not re-sterilize
	Do not re-use
IP22	Ingress Protection Rating 22: • Protected against access of solid foreign objects greater than or equal to 12.5 mm diameter. • Protected against vertically dripping water when the device is tilted 15 °.
IP30	Ingress Protection Rating 30: • Protected against ingress of solid foreign objects greater than or equal to 2.5 mm diameter.
IP54	Ingress Protection Rating 54: • Protected against failure from limited dust ingress. • Protected against failure from splashing water.
FCC ID	An FCC ID is a unique identifier assigned to a device registered with the United States Federal Communications Commission.
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

17. Contact us

Most questions you have about programming the Evoke Closed-Loop Stimulator and Evoke External Closed-Loop Stimulator can be answered by reading this manual or looking at our website, www.saludamedical.com and/or www.saludamedical.com/manuals.

If you have any further questions, please contact your Saluda Medical representative. Alternatively, you can contact us via the details below, or email us at info@saludamedical.com.

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