Evoke® SCS System Clinical Manual

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

Rx Only

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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) 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 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.

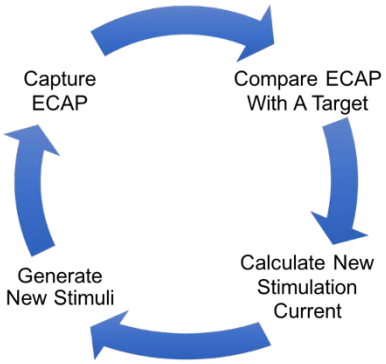


Figure 1.1: ECAP-Controlled Closed-Loop SCS.

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 (stimulation set) can target a different area of the patient's pain.

1.2.5 Multiple waveform options

The stimulation waveform consists of constant current, actively charge-balanced pulses and can be customized by the selection of pulse shape (biphasic or triphasic), polarity (negative or positive first), amplitude (ratio of stimulation current between stimulation sets) and pulse timing (pulse width, frequency, interphase gap and inter-stimulus interval).

1.3 Measurement Features

The Evoke System supports the following types of measurements and data analysis. Refer to the Evoke SCS System Clinical Data 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 CDV 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 7.2). ClearCAP is labeled as 'Virtual Ground' in the CPA.

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 CDV.

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 CDV.

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 CDV.

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 CDV 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 measurement

The vertical alignment of two implanted leads may be estimated using the lead offset measurement feature in the CPA. The measured 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. 3002

The Evoke Closed-Loop Stimulator (CLS) is a totally implanted spinal cord stimulator that connects to the 12C 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 12C 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 12C Percutaneous Lead Kit, 60cm and 90cm

Ref No. 3008/3016/3009/3017

The Evoke 12C 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 two suture anchors and an active anchor with torque wrench to secure the leads, and surgical accessories (epidural needle, tunneling tool, and three stylets) for use during lead placement. Trial leads (Ref No. 3016 and 3017) are provided without the active anchor and torque wrench.

1.4.5 Evoke 12C Lead Extension Kit, 55cm

Ref No. 3011

The Evoke 12C Lead Extensions are used trialing a permanently implanted lead, where the extension is externalized for connection to an eCLS.

1.4.6 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.

1.4.7 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.

1.4.8 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.

1.4.9 Evoke Accessory Belt

Ref No. 3039

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

1.4.10 Evoke Clinical Interface (CI)

Ref No. 3024

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

1.4.11 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.

3 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.

4 Safety Information

Although FDA has determined that the probable benefits outweigh the probable risks, there remains some uncertainty on the long term systemic toxicity risks of the leads, lead extensions, and anchors of the device. As a condition of approval, FDA is requiring the manufacturer to provide additional long term systemic toxicity 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 based on a tablet computer. For non-therapy specific warnings and precautions on this product refer to the device manual accompanying the CI tablet .

4.1 Precautions

4.1.1 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.

4.1.2 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.

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.

4.1.3 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.

4.1.4 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.

4.1.5 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.

4.1.6 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 read 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.

4.1.7 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.

4.1.8 General precautions for the CI

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.

4.1.9 Lead Extension

The Lead Extension should only be used as part of a trial system, to connect the lead to the eCLS (via the lead adaptor). It should not be implanted for connection to an implanted CLS.

5 Introduction

5.1 Evoke Clinical Interface (CI)

The CI is a tablet computer. For full specifications and instructions for use of the 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.

5.2 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.

6 Clinical Interface – General programming using the CPA

6.1 Connecting the CI to the CST and eCLS/CLS

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 the CI instructions (see Section 5.1 for link) to change the time and date.
3. Connect the CST to the CI with the USB connection. See Figure 6.1.

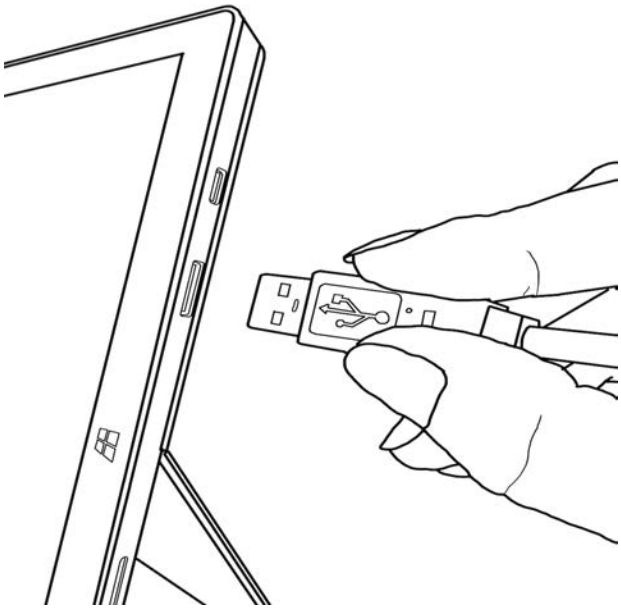


Figure 6.1: Connecting the CST to the CI.

4. Position the CST near the stimulator and double-touch the Evoke Clinical Programing Application (CPA) icon to start the CPA (see Figure 6.2 for the main screen layout).

   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 4.1.7 - Electromagnetic interference (EMI).

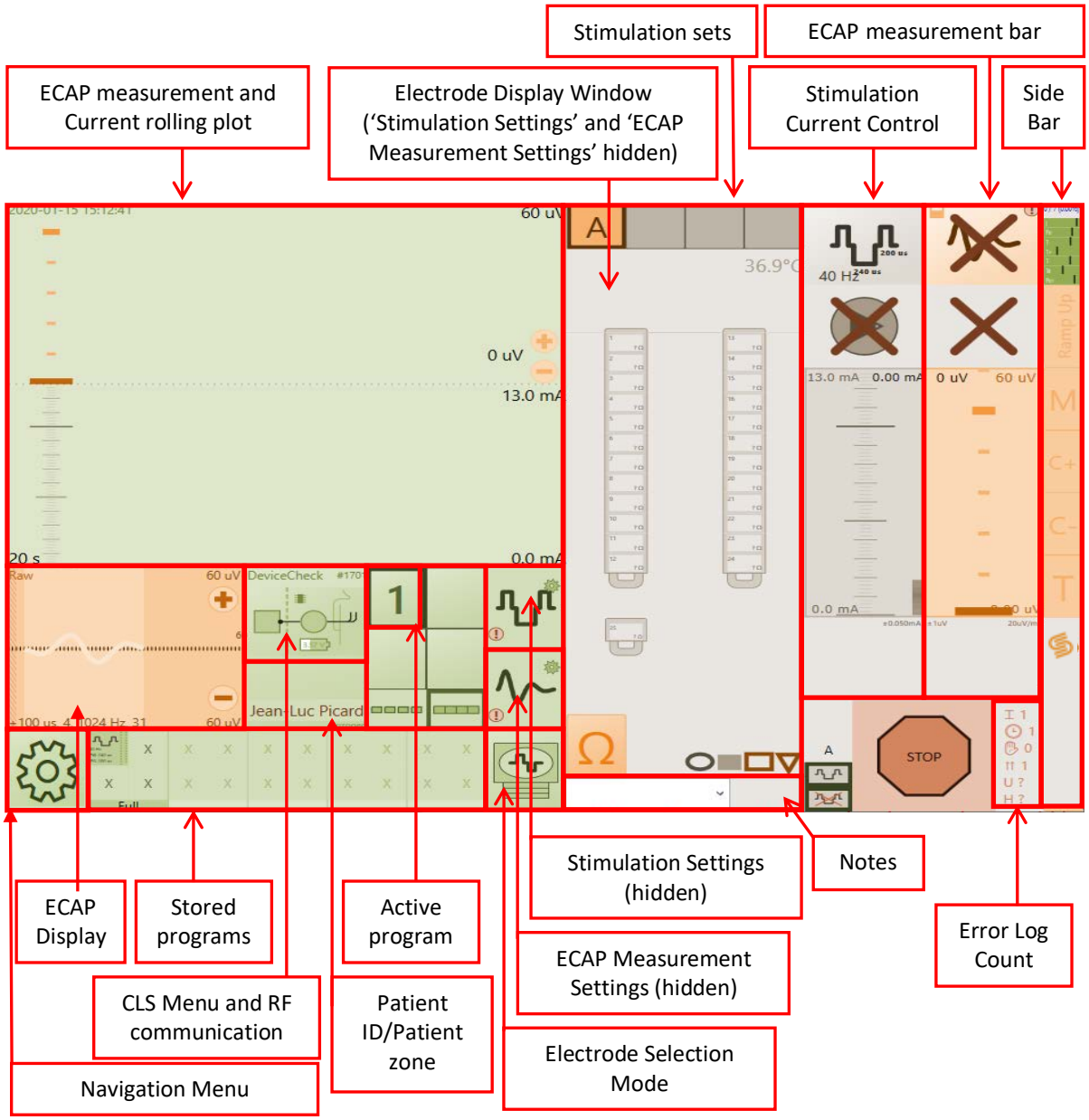


Figure 6.2: Functional layout of the CPA main screen.

5. Choose the appropriate Visit Name from the dropdown menu (see Figure 6.3).
6. Touch *Connect to Implant* to search for nearby stimulators (see Figure 6.3).

   ⚠ **Caution**: Before connecting the CPA to the stimulator, ensure that you have a magnet and paired EPC (see Section 13.1) available at all times during the programming session in case they are needed to stop stimulation (refer to the Evoke SCS System User Manual).

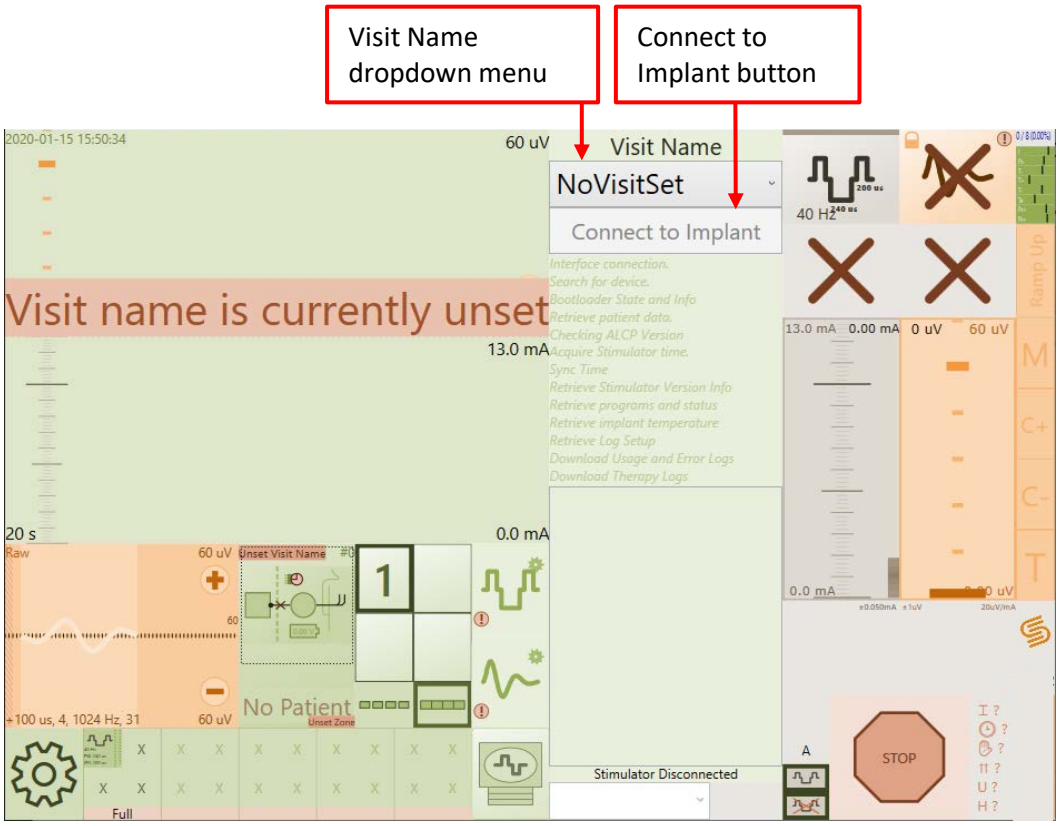


Figure 6.3: Location of the Visit Name dropdown menu and Connect to Implant button.

7. Touch the stimulator serial number that you wish to connect to.
8. The CPA will connect to the stimulator and retrieve any patient data and programs.

   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.

9. The CPA will display the electrode display window when it has successfully connected and downloaded data from the stimulator.

   Note: When the CPA connects to a stimulator it will attempt to download three log files from the stimulator. If any logs cannot be downloaded an error message will be displayed on the ECAP amplitude and current rolling plot (see Section 8.7). To download the logs manually, such as when download fails, refer to Section 8.4.

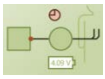
6.2 Set stimulator time

The stimulator time is automatically synchronized to the CI time during connection.

1. Check that the time and date on the CI are correct (top left corner of CPA screen, Figure 6.2). Refer to the CI instructions (see Section 5.1 for link) to change the time and date.
2. Touch the *CLS* icon to open the CLS menu.
3. Touch *Sync Time* in the CLS menu to set the stimulator time to the CI time (if the time is

not already synchronized).

Note: The time error between the CI and stimulator is displayed in brackets.

Note: If out of sync, a red 'clock' icon will be displayed in the CLS icon window  and the time error between CI and stimulator is displayed in brackets in the CLS menu.

6.3 Check stimulator battery voltage

The CLS or eCLS battery voltage are indicated on the CLS icon with a white bar and voltage (3.25 to 4.10 V; Figure 6.4). If the battery voltage is low (<25 % full) the bar will be red. Refer to the Evoke SCS System User Manual for instructions on charging the CLS battery or Section 11.4 for charging the eCLS battery.

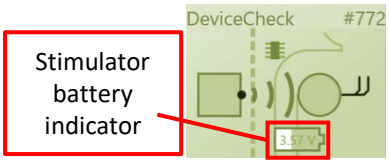


Figure 6.4: CLS icon with stimulator battery voltage indicator.

6.4 Retrieve or set the Patient ID and Patient Zone

6.4.1 For an existing patient

1. On connection to the stimulator the Patient ID and Patient Zone are retrieved and displayed under the CLS icon (see Figure 6.5).

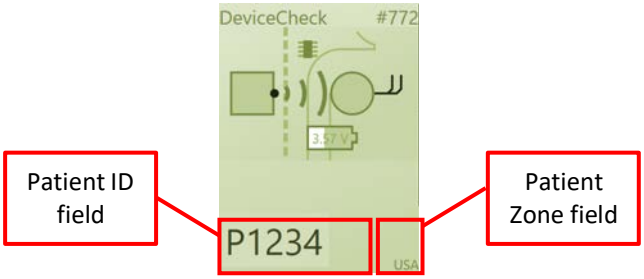


Figure 6.5: CLS Icon with Patient ID and Zone underneath.

2. Check that the correct Patient ID and Patient Zone have been retrieved.

6.4.2 For a new patient

1. For a new patient, touch the *Patient ID* box under the CLS icon (see Figure 6.5).
2. Delete any existing text and enter the new Patient ID.
3. Touch the *Done* button that appears above the Patient ID when you finish typing (see Figure 6.6).

Figure 6.6: CLS Icon with Patient ID and Done button.

Note: If you do not touch the *Done* button, the Patient ID will be automatically updated in the stimulator when you start stimulation.

4. Navigate to the settings page by opening the navigation menu and touching *Settings* (see Figure 6.7). Select the appropriate Patient Zone (see Figure 6.8).

5. Return to the CLS programming page by opening the navigation menu and touching *Programming* (see Figure 6.7).

Figure 6.7: Navigation menu.

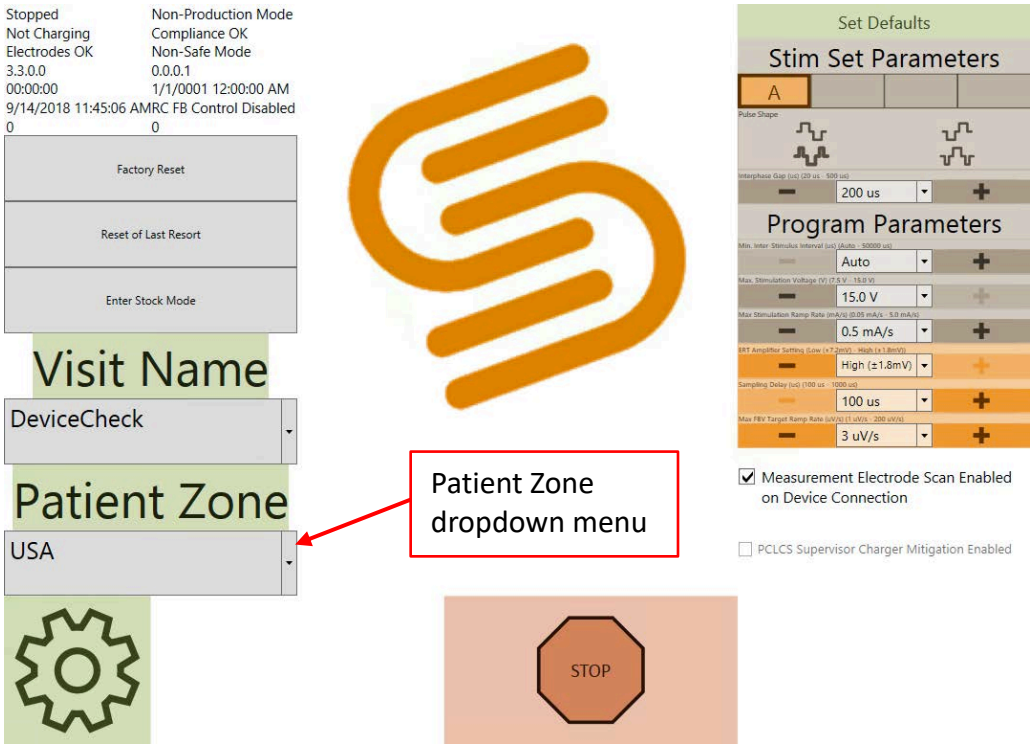


Figure 6.8: Settings menu with Patient Zone dropdown menu highlighted.

6.5 Measure electrode impedances

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

1. Touch the *Impedance* icon .

   Note: The icon will spin during the measurement and stop once it is complete.

2. The impedances on the 24 electrodes and CLS case (E25) will be shown in the electrode display window (see Figure 6.9).

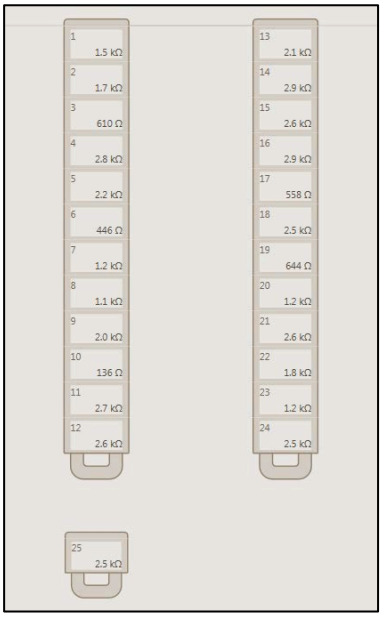


Figure 6.9: Impedances displayed on the 24 electrodes and CLS case (E25).

3. An electrode with a cross through it has high impedance (> 4000 Ω) and may be disconnected. A disconnected electrode shows an impedance of ∞ 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.

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

   ⚠ **Caution:** If the electrodes show an open circuit (i.e. 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.

6.6 Set up lead orientation

1. Touch the handle at the bottom of the lead image to move it up, down, or switch sides to a position that reflects the lead location in the most recent fluoroscopy image (see Figure 6.10). This will aid in determining the best stimulation and measurement electrode combination.
2. If a recent fluoroscopy image is not available then use the lead offset test to estimate the vertical alignment of the implanted leads (see Section 7.8.4).

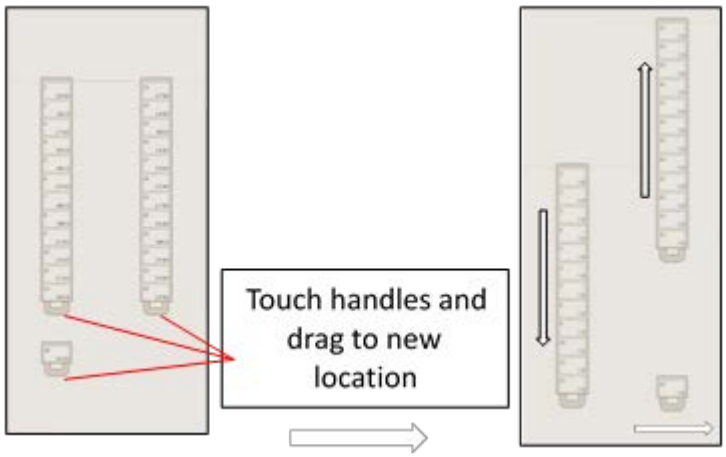


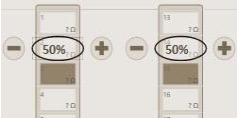
Figure 6.10: You can drag the leads up, down or switch sides.

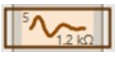
6.7 Programming overview

1. Test stimulation from several electrodes (see Section 6.8 and 6.9) 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 dermatomal pain area(s).
3. Determine the settings that provide a good measurement of the neural response (ECAP) to stimulation (see Section 6.10).
4. Determine the settings for optimum closed-loop stimulation (see Section 6.11 and 6.13).
5. Save the program to the eCLS/CLS memory (see Section 6.15) and proceed to set up a maximum of four programs.

6.8 Choose the stimulation electrodes automatically

1. Stop stimulation if stimulation is running.
2. Change the *Electrode Selection Mode* icon (see Figure 6.2) until the *Automatic Electrode Selection* icon is displayed.
3. In the electrode display window, touch the electrode that you wish to use as the stimulation electrode .
4. Touch the stimulation electrode again to cycle through electrode configurations.

Tripolar: 1 lead	Bipolar: 1 lead	Tripolar: 2 leads	Bipolar: 2 leads
			

5. The CPA will automatically select the stimulation , return , measurement  and reference electrodes for you.
   - You may steer the current between stimulation electrodes (see Section 7.3).
   - You can also manually change the electrode configuration (see Section 8.3), e.g. if you want to move electrodes or add additional stimulation or return electrodes.
6. All settings are set to default values for new programs (see Figure 6.11). To set standard stimulation parameters when reprogramming existing programs, touch *Set Defaults* icons. Otherwise, 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) in the stimulation settings menu (see Section 8.1) and settings menu (see Section 8.6), or adjust measurement parameters in the ECAP measurement and feedback settings menu (see Section 8.2).
7. Restart stimulation with the new stimulation configuration.

   Note: You cannot change the stimulation or return electrodes while stimulation is running.

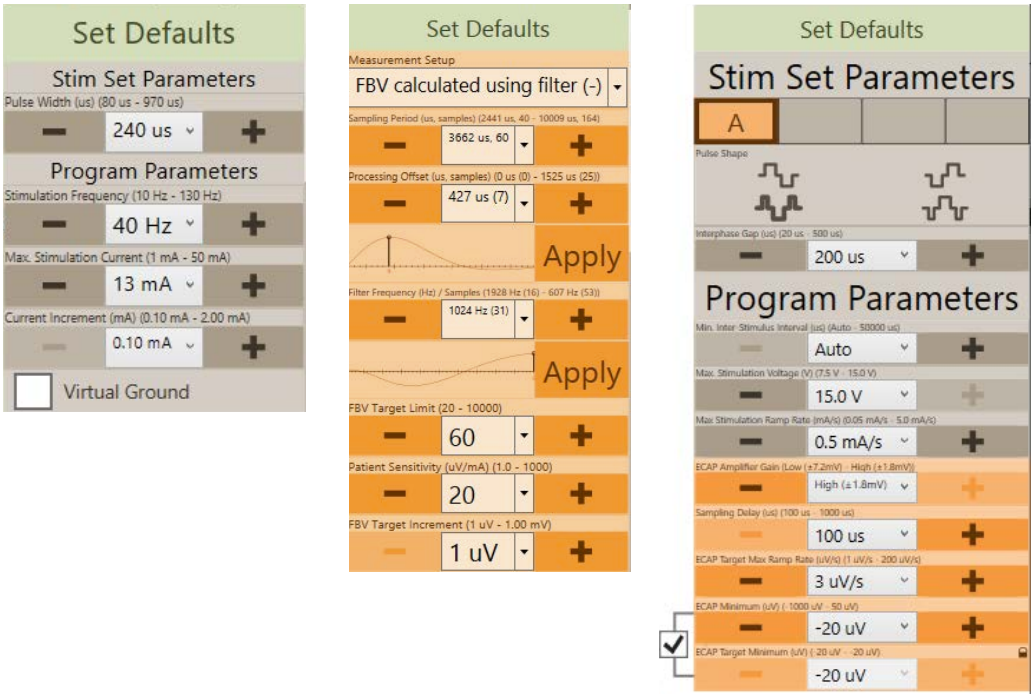


Figure 6.11: *Set Defaults* buttons in the stimulation settings, ECAP measurement and feedback settings, and settings menus (shown from left to right respectively).

6.9 Start and stop stimulation with closed-loop disabled

1. Touch the *Stimulation Settings* icon to change the stimulation parameters (see

Section 8.1). The icon will change to show the *Electrode Display* icon (Figure 6.12). Changes made to the stimulation settings will affect the stimulation current control bar on the right (refer to Figure 6.13 for more details).

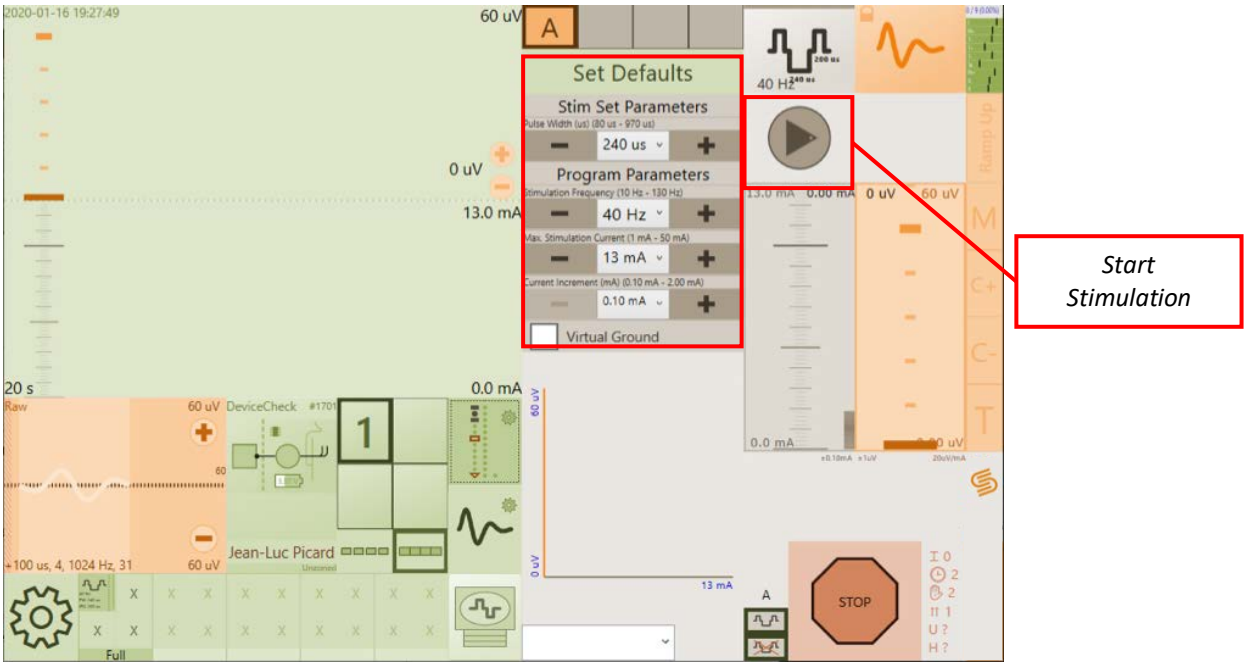


Figure 6.12: Location of the stimulation settings menu and *Start Stimulation* arrow on the CPA.

2. Touch the *Start Stimulation* arrow (see Figure 6.12) to start stimulation with closed-loop disabled.

   Note: The arrow will change orientation to an *Up* arrow for increasing stimulation current, and various areas of the screen will become active, e.g. the ECAP amplitude and current rolling plot.

3. Touch the *Up* arrow to increase stimulation current to the desired level (mA; see Figure 6.13A).

4. Touch the *Down* arrow to decrease stimulation current (Figure 6.13G).

   Note: The current will increase/decrease by the current increment (mA) set (Figure 6.13F). The increment in the current scale is shown on the right side (Figure 6.13D). The scale will extend to the maximum current set (Figure 6.13B).

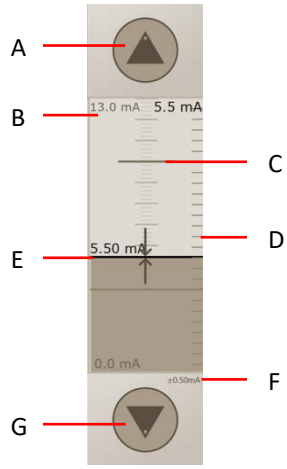
	A: Up arrow
	B: Maximum current
	C: Current scale
	D: Current increment scale
	E: Desired current level
	F: Current increment
	G: Down arrow

Figure 6.13: Features of the stimulation current control.

6.9.1 Stop

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

6.10 Set up ECAP measurement

The stimulator records the ECAP signal and displays a plot of the ECAP on the programming screen (Figure 6.14B). ECAP measurement is only possible for stimulation frequencies of 200 Hz or less (250 Hz or less for Amplitude option, see Section 6.10.1). ECAPs can only be generated and measured above a minimum, threshold current, which varies with different postures and between patients.

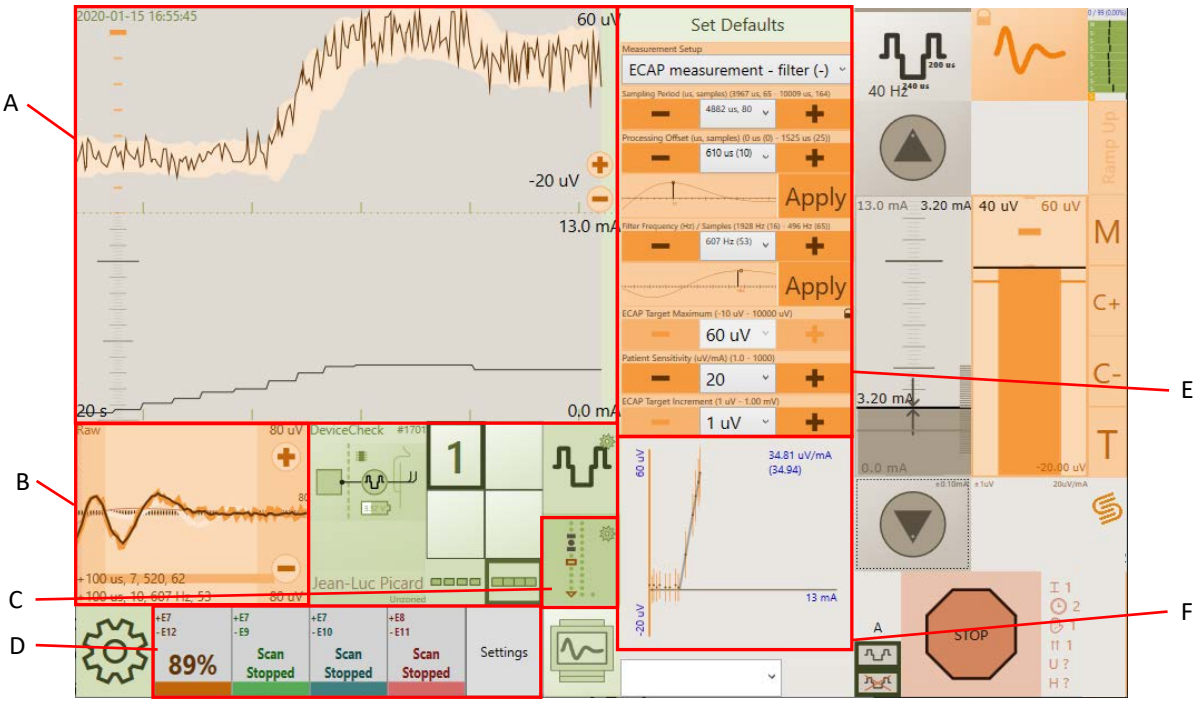


Figure 6.14: A) ECAP amplitude and current rolling plot; B) ECAP display; C) ECAP measurement and closed-loop settings icon location. When selected the icon changes to the *Electrode Display* icon; D) Measurement electrode scan window; E) ECAP measurement and closed-loop settings menu; F) Activation plot.

When stimulation is running, a measurement electrode scan of up to 4 different measurement electrode configurations may be displayed on the ECAP display (Figure 6.15). Refer to Section 6.16 for more information on using the measurement electrode scan to optimize the choice of measurement electrodes and settings.

The ECAP display (Figure 6.15) shows the average ECAP estimate for each measurement electrode configuration (see Section 7.4.1) and the correlation filter used to measure the ECAP. The ECAP display shows the currently in use and recommended measurement settings for the ECAP, the sampling period, and buttons to zoom in and out of the Y-scale.

> **Note:** ECAP measurements and the recommended measurement settings only apply to the selected measurement electrode configuration.
>
> **Note:** 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 (see Section 7.4.1.1).

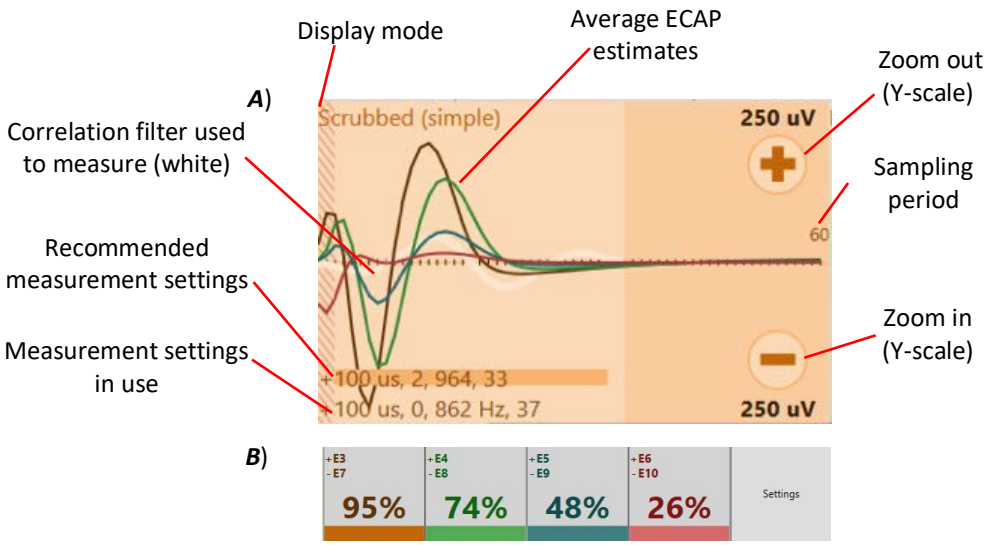
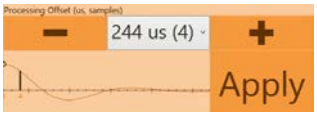


Figure 6.15: A) ECAP display for the selected measurement electrode configuration (orange) and 3 other configurations (green, blue and red). Note the measurement settings, in order, are: sampling delay, processing offset (number of samples), filter frequency, and number of filter samples; B) Measurement electrode scan window showing measurement electrode configurations, Signal Quality Indicator (SQI) and Settings button. Refer to Section 7.4 for more information.

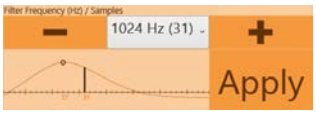
1. Start stimulation and increase the stimulation current (see Section 6.9) so that a clear ECAP signal is visible and/or above the patient's perception threshold.
2. Use the ECAP display and measurement electrode scan window (Figure 6.15) to determine the measurement electrode configuration with the optimal ECAP based on size, shape, and/or largest Signal Quality Indicator (SQI) value (see Section 6.16).
    a. Enabling ClearCAP (Virtual Ground) may improve ECAP measurement (see Section 7.2 for more information).
3. Change the *Electrode Selection Mode* to (see Section 8.3) and touch the required measurement electrode.
4. Change the *Electrode Selection Mode* to (see Section 8.3) and touch the required reference electrode.

    Note: The measurement and reference electrodes may not be moved to be adjacent to the stimulation or return electrodes.

5. Touch the *ECAP Measurement and Closed-loop Settings* icon to open the measurement and feedback settings menu (Figure 6.14E). The icon will change to show the *Electrode Display* icon (Figure 6.14C).

6. Touch *Apply* to set the optimal Processing Offset 

. The open circle on the plot is the recommended offset (peak of plot), while the black line is the offset setting in use.

7. Touch Apply to set the optimal Filter Frequency 

. The open circle on the plot is the recommended frequency (peak of plot), while the black line is the frequency setting in use.

8. Ensure the applied measurement settings match the recommended measurement settings (Figure 6.16), 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 (see Section 8.2).

   Note: The default filter has a negative first peak (see Figure 6.16). In some cases filter alignment may be improved by flipping the filter the first peak is positive. This is done by changing the measurement setup to 'ECAP calculated using filter (+)' from the Measurement Setup options (see Section 8.2). See Section 6.10.1 for other ECAP measurement options.

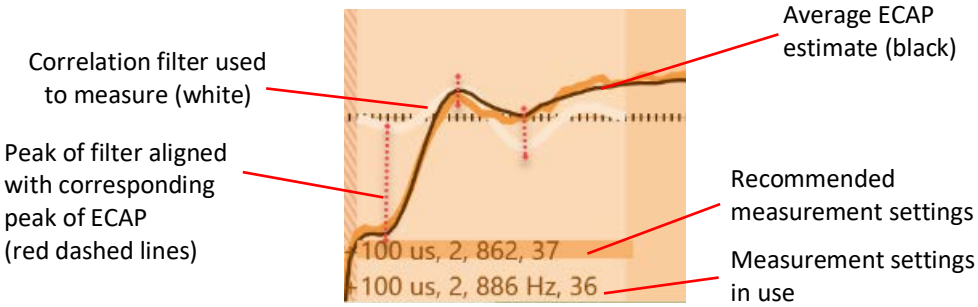


Figure 6.16: ECAP display with a well matched filter (-).

9. The ECAP amplitude and current rolling plot (Figure 6.14A) displays the ECAP amplitude (top) and current (bottom) over time. You can use the and buttons to adjust the minimum ECAP measurement value displayed. ECAP amplitudes below the ECAP Minimum (dotted black line, see Sections 6.10.1 and 8.6) are shaded in red (Figure 6.17).

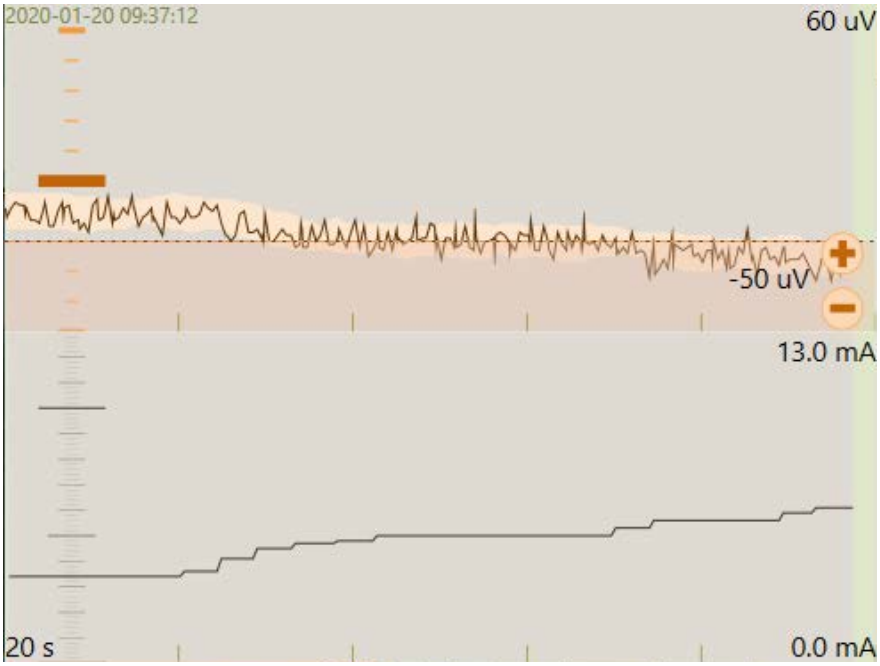
10. 

Figure 6.17: The ECAP measurement (top) and current (bottom) rolling plot.

6.10.1 ECAP measurement options

There are four measurement setup options in the Measurement and Feedback settings menu (see Section 8.2):

1. **ECAP Raw Data Logged**

   The ECAP signal is recorded and displayed in the ECAP display, but the system does not measure the amplitude of the ECAP. For this option, closed-loop is disabled, and stimulation frequency is available up to 250Hz.

2. **ECAP calculated using 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 (see Section 6.10, steps 6 and 7). 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.

3. **ECAP calculated using 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 (see Section 6.10, steps 6 and 7). 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.

4. **ECAP calculated using Amplitude**

The ECAP amplitude is measured from the peak-to-peak amplitude of the ECAP signal within the Processing Period

(see Section 8.2) and there will be no recommended measurement settings (see Figure 6.18). 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 (e.g. Figure 6.18).

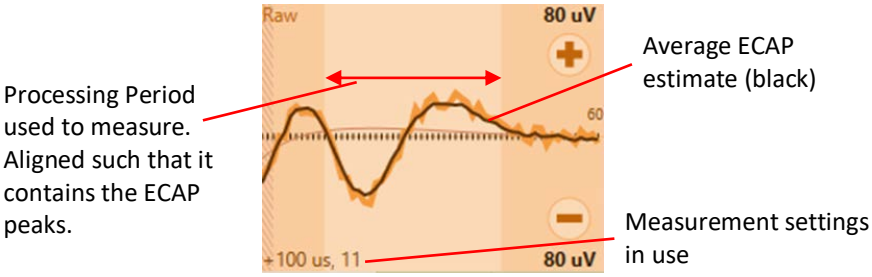


Figure 6.18: ECAP display with a well matched amplitude measurement.

Note: Some artefact signals may introduce an offset in the measured ECAP amplitudes, including negative offsets with the correlation filter (see Figure 6.17). Ensure that all ECAP amplitudes are measured by setting the ECAP minimum to a value less than the ECAP amplitudes measured during collection of the activation plot and posture testing (see below and Section 8.2).

Other Measurement and Feedback settings (Section 8.2) for ECAP measurement include:

1. **Sampling Period**

   The number of samples of the signal to record (see Section 8.2). The Sampling Period (default 3662 µs) 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) – refer to Figure 6.16 and Figure 6.18 for optimal measurement examples.

Other settings from the Settings screen (Section 8.6) for ECAP measurement include:

1. **Sampling Delay**

   The amount of time for the system to wait, following the stimulus pulse, before recording the signal (see Section 8.6). Consider increasing this from default (100 µs) if the Processing Offset cannot be increased enough for optimal measurement of the ECAP (refer to Figure 6.16 and Figure 6.18 for optimal alignment examples).

2. **ECAP Amplifier Gain**

   The voltage range of the signal that can be recorded (see Section 8.6). The default setting is 'High (± 1.8mV)'. Consider setting this to 'Low (± 7.2 mV)' if the ECAP signal is clipping (see Section 12.5).

3. **ECAP Minimum**

   The minimum ECAP amplitude recorded by the stimulator. The default setting is -20 µV. Consider changing this to a value less than the ECAP amplitudes measured during collection of the activation plot and posture testing (see Section 12.5) to ensure that ECAP amplitude is recorded over the full range of activation

4. **ECAP Target Minimum**

   The minimum ECAP target that can be set with the CPA or EPC when closed-loop is enabled. The default setting is to always link this value to the ECAP Minimum, with a default value of -20 µV. Consider de-linking this setting and changing to a value just below the ECAP amplitude at the ECAP threshold to ensure the target cannot be set to a low value that results in no therapy.

6.11 Set up closed-loop stimulation

The settings for closed-loop stimulation vary between patients and for different electrode configurations. Settings can be optimized in the measurement and feedback settings menu (Figure 6.14E). These settings depend on the sensitivity of the ECAP to changes in current.

The CPA can measure ECAP sensitivity as the current is varied (see Figure 6.14F), following these steps:

1. Optimize the ECAP measurement (refer to Section 6.10).
2. Increase current from near paresthesia threshold to a strong level (e.g. the maximum that the patient could tolerate for one minute), refer to Section 7.6 for information on collecting the activation plot. From the activation plot, calculate the therapeutic window, which is the difference between the ECAP amplitudes at threshold and maximum.
3. The activation plot will display the ECAP amplitude as a function of current, and the measured sensitivity is displayed on the plot (see Figure 6.19).
4. 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 paraesthesia threshold. Above this inflection the ECAP amplitude should increase linearly with the stimulation current (see Figure 6.19).
   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 (see Section 8.1) 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.

5. 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 6.10) and/or adjusting the stimulation settings (see Section 6.8).

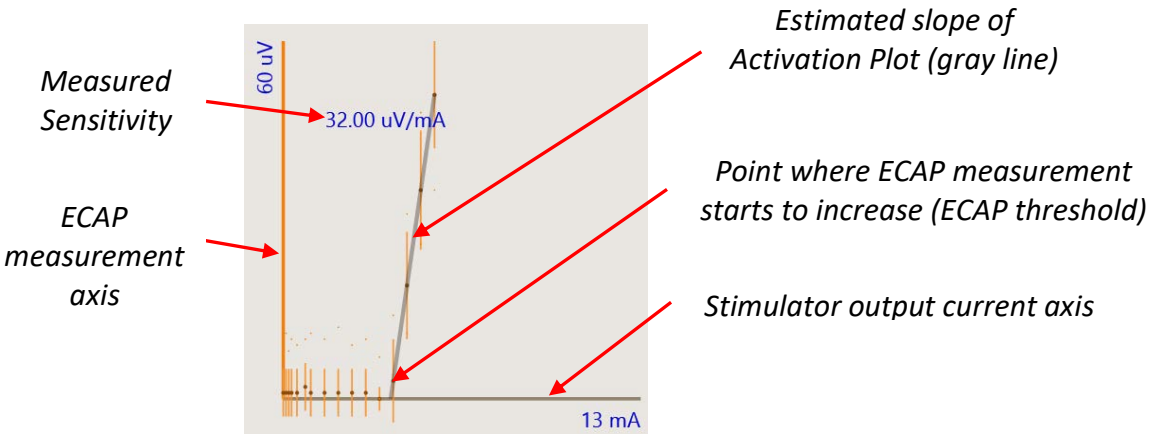


Figure 6.19: The Activation plot – ECAP amplitude (µV) versus Current (mA).

6. 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 measurement and feedback settings menu (see Section 8.2). The minimum patient sensitivity is 14 µV/mA.

6.12 Set appropriate limits and increments

Prior to final testing, appropriate limits and increments should be set for each program that the patient has saved to their stimulator (see Section 6.15). Refer to Table 6.1 for guidelines on determining appropriate values.

The limits (both stimulation current and ECAP target) 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), and adjusted accordingly if required.

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, ensuring that it is not too large (e.g. large 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 (see Section 6.13 and 6.14).

Table 6.1: Guidelines for setting appropriate limits and increments for stimulation current and ECAP target.

Parameter	Guideline
Maximum Current Limit (mA) (see Section 8.1)	Set to the first available value ≥1.5 x stimulation current at the Maximum activation plot level, measured while the patient is in the sitting posture (see Section 7.6).
ECAP Target Maximum (µV) (see Section 8.2)	Set to the first available value such that the ECAP Target Maximum > Maximum/1.5 and ECAP Target Maximum > Comfort+, (where Maximum and Comfort+ refer to the activation plot levels measured while the patient is in the sitting posture, see Section 7.6).
ECAP Minimum (µV) (see Section 8.6)	Set to the highest value such that the ECAP Minimum ≤ minimum ECAP amplitude recorded during collection of the activation plot and posture testing (see Section 7.6).
ECAP Target Minimum (µV) (see Section 8.6)	Link to ECAP Minimum, or if necessary, de-link and set to the highest value such that the ECAP Target Minimum ≤ ECAP amplitude at the ECAP threshold (see Section 7.6).
Current Increment (mA) (see Section 8.1)	Set between 0.1 and 0.3 mA, depending on the current range between Threshold and Maximum activation plot levels in the sitting posture (see Section 7.6). 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) (see Section 8.2)	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, see Section 7.6).

6.13 Enable closed-loop stimulation

Once all the settings for the program have been set up and the criteria for the activation plot have been met (see Section 6.11), you may evaluate closed-loop operation. It is important to test the effectiveness of the closed-loop control with the patient in various postures.

1. Start stimulation and set the current to a comfortable level.
2. Touch the *CL* icon to enable closed-loop stimulation (see ECAP amplitude bar in Figure 6.2).
3. When closed-loop is enabled, the rolling plot will display with an orange background and the current will vary over time (Figure 6.20). The ECAP amplitude will vary around the target level (Figure 6.22). If the ECAP variability is increased after closed-loop is enabled:
    a. You may increase the Patient Sensitivity setting (see Section 8.2) to reduce this

variability.

b. If the measured sensitivity is low (near 10 µV, see Section 6.11) and the stimulation frequency is low (e.g. 10-20 Hz), try increasing the stimulation frequency (see Section 8.1) 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 6.10 onwards).

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 (Figure 6.22), and changes in current should track the patient's movement (Figure 6.21). If they don't, you may need to adjust the ECAP measurement settings (see Section 6.10).
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 (see Section 8.2).

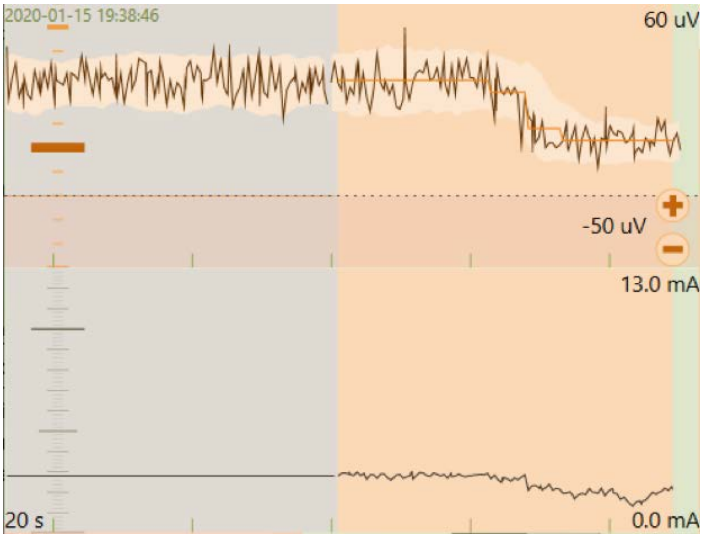


Figure 6.20: Rolling plot with closed-loop disabled (gray background) then closed-loop enabled (orange background). *Top:* ECAP amplitude (black line) and target value (orange line); *bottom*: Current (black line).

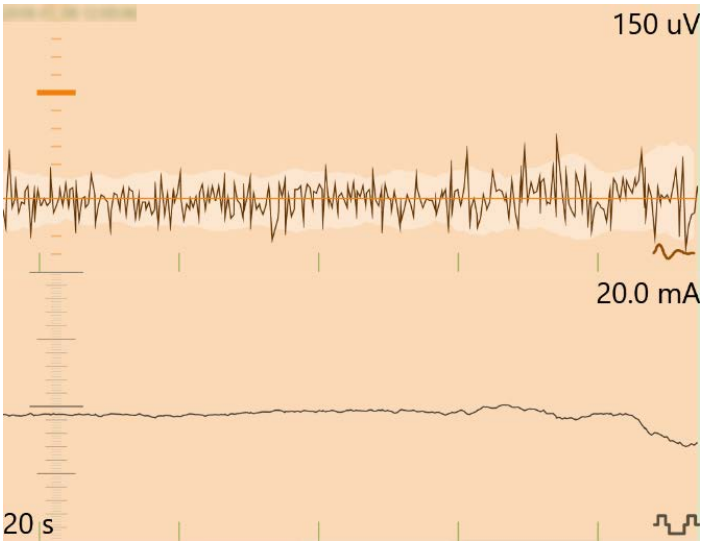


Figure 6.21: Rolling plot (with closed-loop enabled) while the patient is transitioning from sitting (earlier in time, to the left, where current is higher) to supine (later in time, to the right, where current is lower).

6.14 Start and Stop stimulation with closed-loop enabled

Closed-loop stimulation may be changed using the ECAP amplitude bar (Figure 6.22).

1. If therapy is stopped, touch the S*tart CL Stimulation* arrow .

   Note: The arrow will change orientation to an *Up* arrow for increasing the ECAP amplitude target, and various areas of the screen will become active, e.g. the ECAP amplitude and current rolling plot and ECAP display.

2. Touch the *Up* arrow to increase the target to the desired level (µV; Figure 6.22A).

3. Touch the *Down* arrow to decrease the target (Figure 6.22I).

   Note: The target will increase/decrease by the ECAP Target Increment (µV*)* set (see Section 8.2). The increment value and level are shown on the left side of the ECAP amplitude bar (Figure 6.22G).

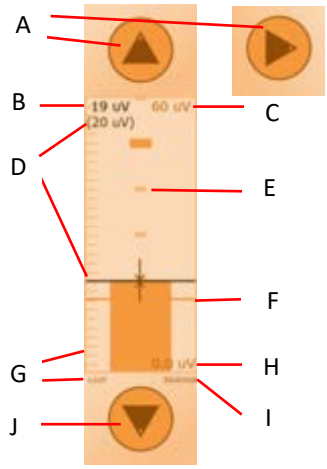
	A: Up arrow / Start CL stimulation
	B: Average ECAP measurement
	C: Maximum ECAP target
	D: Desired target value / level
	E: ECAP measurement scale
	F: ECAP measurement
	G: Target increment scale / value
	H: Minimum ECAP target
	I: Patient sensitivity setting
	J: Down arrow

Figure 6.22: Features of the ECAP amplitude bar.

6.14.1 Stop

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

6.15 Save a program to the stimulator

The CLS and eCLS can each hold up to four different programs. The four program slots display the programs currently stored in the CLS or eCLS (see Figure 6.23). Any program that is run on the stimulator (stimulation turned on) is automatically saved to the selected program slot.

Figure 6.23: Location of the program slots and save slots on the CPA.

6.15.1 To add a new program

1. Touch the desired *program slot* (see Figure 6.23); you will see a number corresponding

to that program slot appear in the box.

2. Select electrodes and change settings as required.

   Note: If a program on the CPA has not been run on the stimulator (such as a new program, or one that has been modified), it will be shown in red in the corresponding program slot. Once a program has been run, its number will be shown in green (see Figure 6.24), and it will be saved to the stimulator.

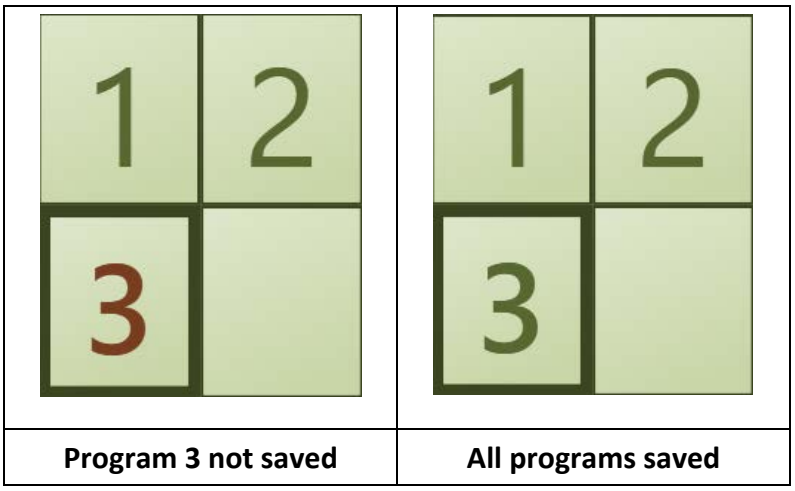


Figure 6.24: (Left) Program 1 and 2 are saved on the stimulator while program 3 is red because it is not saved to the stimulator. (Right) Program 3 has been run and is now green; all three programs are currently saved on the stimulator.

6.15.2 To copy settings from one program to another

1. Drag the program number to the desired program slot for the new program.

   Note: You should save the programs to a save slot (see Section 6.15.3) before overwriting a program in case you want to restore a previous one.

6.15.3 To save a program into the save slots

After the CPA connects or disconnects from a stimulator, all the programs in the program slots are saved to a save slot and also saved as a program file on the CI.

You can manually create a backup of programs from the stimulator or save a newly created program for later use in the save slots. This also stores a copy of the programs as a file on the CI, which can be retrieved in a future programming session (see Section 6.15.4).

1. Touch an empty *save slot* and select *Save* to save all the current programs to that slot (see Figure 6.23).

   Note: If a save slot that has already been used is selected, the existing program(s) saved in that slot will be overwritten and a new program file will be saved on the CI, however, this does not overwrite the previous program file.

⚠ **Caution:** The programs in the save slots will only be saved locally on the CI you use to program the patient. If you use more than one CI in your clinic, the programs in the save slots will not be available on any other CI.

6.15.4 To load and restore programs from the save slots

To load a saved program file from the CI into a save slot:

1. Touch a *save slot* and choose *Load From File,* locate and select the file, then touch *Open.*

   Note: If a save slot that has already been used is selected, the existing program(s) saved in that slot will be overwritten and a new program file will be saved on the CI, however, this does not overwrite the previous program file.

To restore a saved program from a save slot into the stimulator:

1. If restoring a single program, first touch the *program slot* you want to load the saved program into.
2. If restoring a single stimulation set (see Section 7.5), first select the stimulation set you want to load the saved stimulation set into.
3. Touch the desired *save slot* and choose *Restore.*
   a. You may restore all the programs (up to 4) saved in that save slot, a single program or a single stimulation set.
4. Turn stimulation on to load the program into the stimulator (individually, for each program that you want to restore). See Figure 6.24 for identifying whether a program has been saved to the stimulator.

6.15.5 To clear the program from a save slot

1. Touch the desired *save slot* and choose *Clear.*

   Note: Clearing the save slot does not delete the program file saved on the CI.

6.16 Create a new program or use programming features and settings

1. To create a new program return to Sections 6.7 to 6.15.
2. To adjust the settings for the programs or stimulator refer to Section 8.
3. To access other programming features refer to Section 7.

6.17 Disconnect from the stimulator and close the CPA

1. Touch the *CLS* icon and select *Disconnect* at the end of the programming session.
2. Touch the navigation menu icon and select *Quit* to close the CPA.

7 Clinical Interface – Programming features

7.1 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 7.1 for example) by the selection of the following parameters: pulse shape, polarity, stimulation current, and pulse timing.

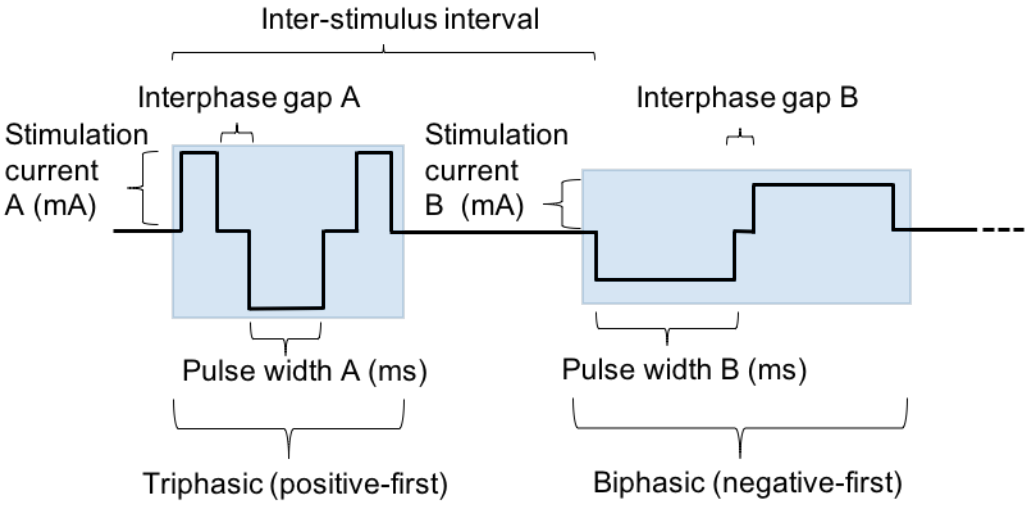


Figure 7.1: Example stimulation waveform for a program with two stimulation sets. Stimulation set A is shown with triphasic and positive-first, and stimulation set B is shown with biphasic and negative-first. Each stimulation set may also have a different stimulation current, pulse width, and interphase gap. The inter-stimulus interval is configurable for each program.

7.1.1 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 stimulation set (see Section 8.6 to set the pulse shape and polarity, and Figure 7.1 for examples).

7.1.2 Stimulation current

When closed-loop is disabled, the stimulation current is fixed at the level chosen by the user (see Section 6.9). 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 (see Section 6.14). The stimulation current can be customized for each stimulation set (see Section 7.5.3, e.g. Figure 7.1), such that the ratio of stimulation currents between each stimulation set is kept constant.

7.1.3 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 stimulation set (see Section 8.1, e.g. Figure 7.1).

7.1.4 Interphase gap

The interphase gap is a pause between each phase when no current is delivered (e.g. Figure 7.1). The interphase gap can be customized for each stimulation set (see Section 8.6).

7.1.5 Inter-stimulus interval

In programs with 2 to 4 stimulation sets (see Section 7.5), the inter-stimulus interval sets the time between the start of the pulses from one stimulation set and the start of the next stimulation set (e.g. Figure 7.1). The inter-stimulus interval can be customized for each program (see Section 8.6). In programs with one stimulation set, this parameter is not used.

7.1.6 Stimulation Frequency

Each stimulation waveform as defined by the above parameters (e.g. Figure 7.1) repeats at a set frequency. The stimulation frequency can be customized for each program (see Section 8.1).

7.2 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 6.10). The Reference electrode is set as the input electrode for ClearCAP stimulation , however, the measurement functionality of the Reference electrode remains unchanged (see Section 8.3). ClearCAP is labeled as ‘Virtual Ground’ in the CPA 'Stimulation settings menu’ and may be enabled or disabled for each program (see Section 8.1).

Note: ClearCAP cannot be enabled or disabled during stimulation.

Note: The Maximum Stimulation Voltage must be 15 V if ClearCAP is enabled (see Section 8.6).

⚠ **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 7.2).

- ECAP amplitude variability (refer to rolling plot in Figure 6.14A) should be unchanged or reduced with ClearCAP enabled.
- Criteria described in Sections 6.10 to 6.14 are met with ClearCAP enabled.

  Note: If the criteria above cannot be met, ClearCAP should be disabled for the current program configuration.

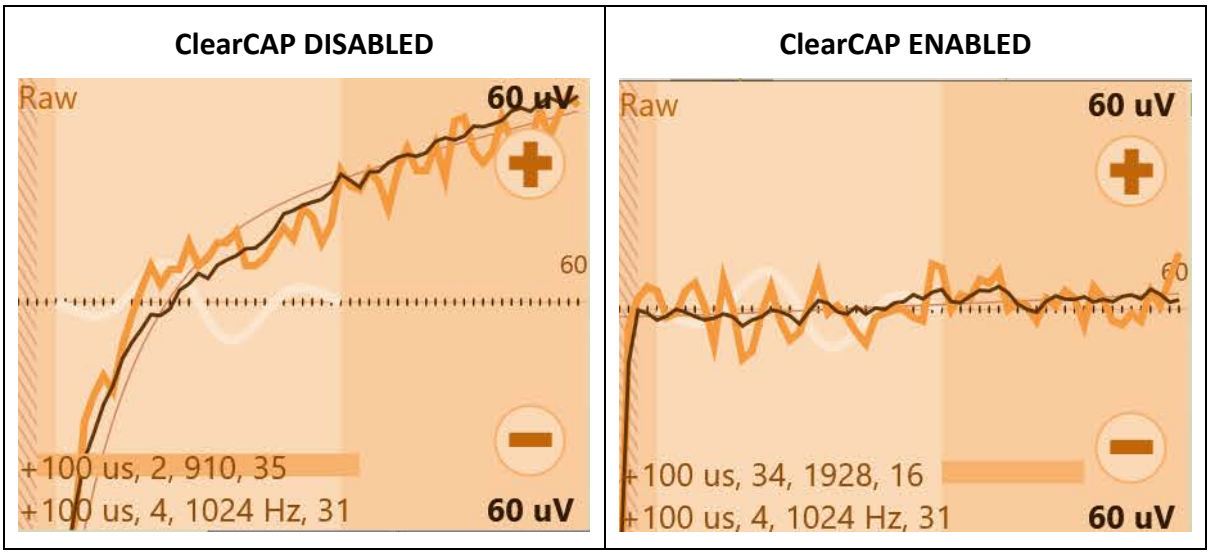


Figure 7.2: ECAP Display plot showing an example of artefact magnitude decreasing when ClearCAP is enabled.

7.3 Current steering

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

1. Select 2 to 4 stimulation electrodes. The stimulation electrodes will now be displayed with a % value and a '-' icon on the left and '+' icon on the right (see Figure 7.3).
2. The % value represents the % of the total current going to that stimulation electrode.
3. To deliver more current to an electrode touch the '+' icon. To deliver less current to an electrode touch the '-' icon. The % of current delivered at the other stimulation electrodes will automatically adjust to keep the total at 100%.

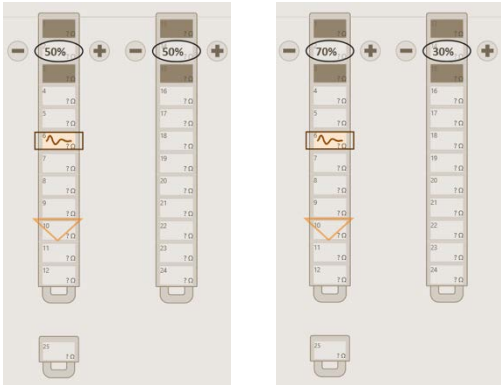


Figure 7.3: Current steering: 50:50 (%) on the left and 70:30 (%) on the right.

7.4 Measurement electrode scan

The measurement electrode scan allows ECAPs from multiple electrode configurations to be displayed on the ECAP display (7.4.1.1) at the same time. It is intended to assist in optimizing the choice of measurement electrodes and settings. By default, the measurement electrode scan will be automatically started when stimulation is started.

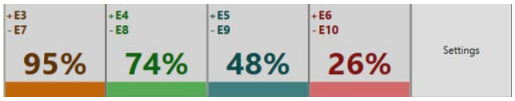
The measurement electrode scan consists of up to four measurement electrode configurations: the configuration selected by the user and 1 to 3 other configurations. The configurations used in the scan are displayed in the measurement electrode scan window (Figure 7.4) along with the Signal Quality Indicator (SQI, see Section 7.4.2)

The electrodes used in the scan are based on the location of the stimulation, measurement and reference electrodes that are selected in the electrode display window (Figure 6.2). See Section 7.4.3 for the methods used to choose the scan electrodes.

Note: To perform a Measurement Electrode Scan:

- The selected stimulation, measurement, and reference electrodes must be on the same lead.
- Only 1 stimulation electrode must be selected.
- The measurement electrode must not be adjacent to the stimulation or return electrode.
- The reference electrode must not be on the case (E25)
- The measurement electrode must be between the stimulation and reference electrodes

A)



B)

Figure 7.4: Measurement electrode scan window showing: A) 4 electrode configurations, SQI values and Settings button; B) Scan stopped; C) '-' indicates not enough stimuli to calculate SQI, grayed slots indicates that the scan is disabled; D) SQI = 0% indicates no ECAP has been detected, blank slot indicates there is no valid scan configuration available; E) colored bar indicates the electrode configurations that are plotted on the ECAP display.

7.4.1 ECAP and artifact estimation

The signal recorded by the CLS or eCLS 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 (see Section 7.4.1.1) and the quality of the ECAP may be calculated (see Section 7.4.2).

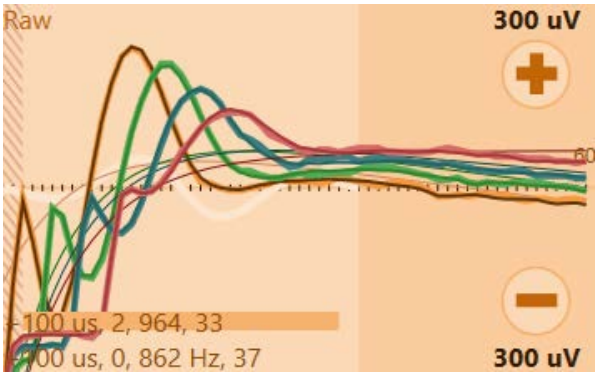
7.4.1.1 ECAP display

The ECAP display shows signals from up to 4 measurement configurations represented by 4 colors. The display shows the 'latest' from one stimulation pulse, 'average' from 16 stimulation pulses and an 'estimate' calculated from the latest or average signals.

1. Touch an electrode configuration slot on the measurement electrode scan window to turn the ECAP display off or on for that configuration (see Figure 7.4E).
2. Touch the ECAP display to toggle between three modes of ECAP display (see Figure 7.5): Raw, Scrubbed (simple) and Scrubbed (detailed).

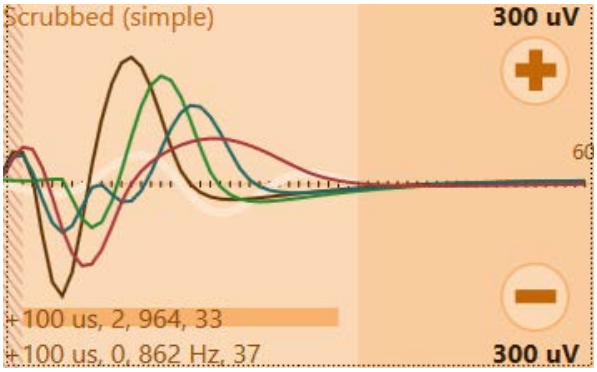
A) Raw

- latest recorded signal (light line, e.g.)
- average recorded signal (dark line, e.g.)
- average artifact estimate (thin line, e.g.)



B) Scrubbed (simple)

- average ECAP estimate (dark line, e.g.)



C) Scrubbed (detailed)

- latest ECAP estimate (light line, e.g.)
- average ECAP estimate (dark line, e.g.)
- average recorded signal with average artifact estimate subtracted (thin line, e.g.)

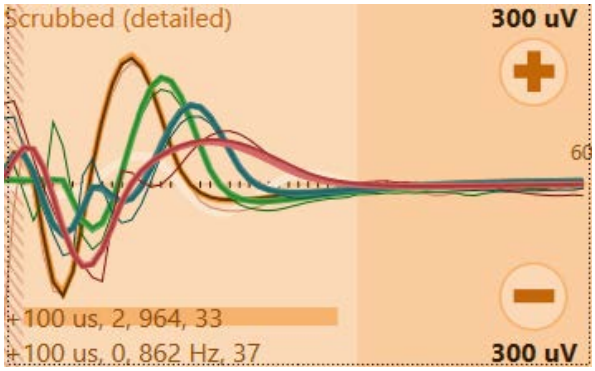


Figure 7.5: ECAP display: A) Raw; B) Scrubbed (simple); C) Scrubbed (detailed); with up to 4 colors representing each measurement configuration.

Note: 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.

7.4.2 Signal Quality Indicator (SQI)

The SQI is a relative measure of the quality of the ECAP that can be estimated from the recorded signal. The SQI is rated between 0% for no ECAP estimate possible, to 100% for the

best ECAP estimate possible. The SQI may be compared across different measurement configurations to determine the optimal settings for ECAP measurement.

> **Note**: If an ECAP is present in the ECAP signal, the SQI value may gradually increase with time (i.e. if the confidence in the ECAP estimate increases with more stimulation pulses). The SQI value will eventually plateau, but will reduce slowly if the quality of the ECAP reduces and the confidence in the ECAP estimate decreases.

7.4.3 Measurement electrode scan settings

1. Touch the *Settings* button to change the measurement electrode scan settings.

<table>
<tr><th>Button</th><th>Action</th></tr>
<tr><td>Clear SQI</td><td>Clear the SQI values and restart the SQI calculations. The SQI will be displayed as ‘-’ until ECAPs are received.</td></tr>
<tr><td>Stop / Start Scan</td><td>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.</td></tr>
<tr><td>Position Configuration</td><td>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 Figure 7.6):
<table>
<tr><th>Button</th><th>Measurement</th><th>Reference</th></tr>
<tr><td>Optimal*
(#electrodes from stimulation)</td><td>3
3
4
4</td><td>5
6
7+
case (E25)</td></tr>
<tr><td>Fixed Measurement^
(#electrodes from selected)</td><td>As selected</td><td>1 closer
1 further
2 further</td></tr>
<tr><td>Fixed Reference^
(#electrodes from selected)</td><td>1 closer‡
1 further
2 further</td><td>As selected</td></tr>
<tr><td>Fixed Distance^
(#electrodes from selected)</td><td>1 closer‡
1 further
2 further</td><td>1 closer
1 further
2 further</td></tr>
</table></td></tr>
<tr><td>Disable / Enable Scan</td><td>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. This control is also available in the CLS menu (see Section 8.4).</td></tr>
</table>

***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 or return 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	-E12	-E12	-E12	-E12	-E9	-E8	-E10	-E11	-E9	-E8	-E10	-E11

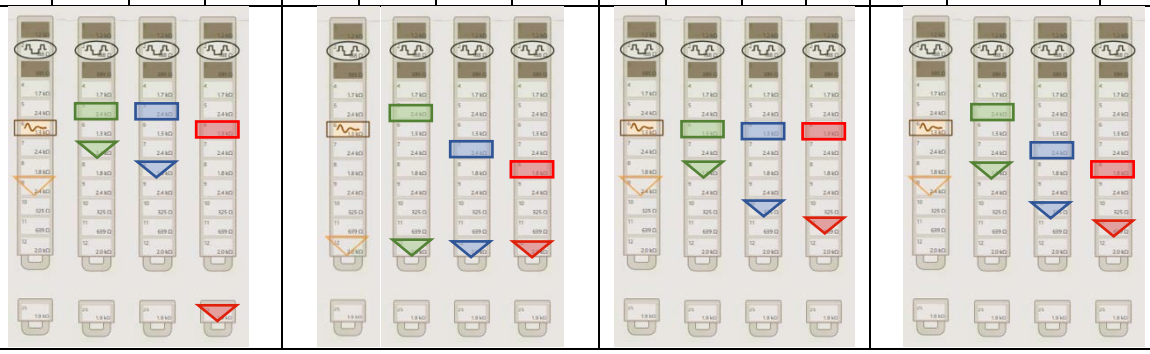


Figure 7.6: Examples of Measurement Electrode Scan position configuration methods when the stimulation electrode is at E2.

7.4.4 Measurement electrode scan enabled on device connection

The measurement electrode scan is enabled by default when you connect to a stimulator. You may change the default in the settings screen (see Section 8.6).

1. Navigate to the settings page by opening the navigation menu and touching *Settings* (see Figure 6.7).
2. You may change the setting *Measurement Electrode Scan Enabled on Device Connection* by ticking the box (enabled, default) or unticking the box (disabled).
3. Return to the CLS programming page by opening the navigation menu and touching *Programming* (see Figure 6.7).

7.5 Interleaved stimulation

A program may contain several interleaved stimulation sets (SS), targeting several areas of pain. The CPA has the ability to concurrently run up to four (4) stimulation sets per program.

Refer to Figure 7.7 below for controls related to interleaved stimulation.

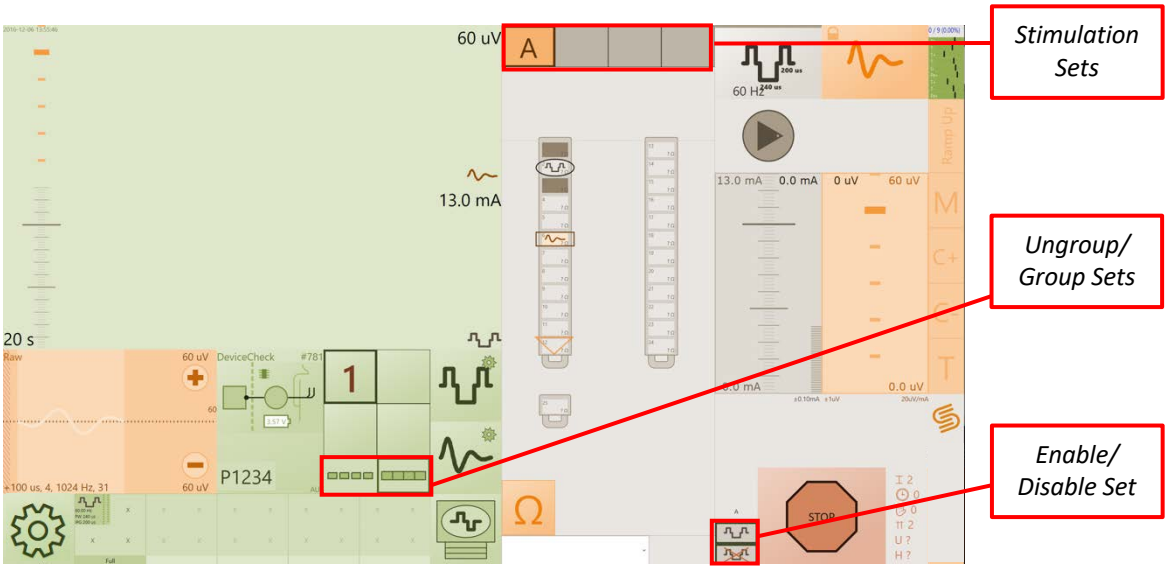


Figure 7.7: Location of controls related to interleaved stimulation in the CPA.

7.5.1 Set up interleaved stimulation

To set up multiple stimulation sets in a program:

1. Select a program, and the desired stimulation set (A, B, C or D).
    a. Configure the program with the desired stimulation and measurement settings (see Sections 6.8 to 6.11).
    b. Increase the current to the patient perception threshold and touch the *Threshold* button (see Section 7.6).
2. Stop the current stimulation set, select the next stimulation set, and ensure that the stimulation sets are set to run in *Ungrouped* mode ( ).
    a. Configure the new stimulation set with the desired stimulation settings (see Sections 6.8 to 6.9).
    b. Set the current to the patient perception threshold and touch the *Threshold* button (see Section 7.6). The button will be a darker orange because it has already been marked in other stimulation sets.

    Note: Frequency, maximum current, and current increment are equal across stimulation sets, while pulse width may be set independently.

    Note: The electrode settings used in other existing stimulation sets will appear in the background (Figure 7.8), while the active set will be shown.
3. Repeat Step 2 until up to four Stimulation Sets have been set up.
4. Select a stimulation set and increase current to the previously marked threshold and leave stimulation on.

5. Repeat Step 4 for each remaining stimulation set in the program until all have been set to the threshold level.

6. Set the stimulation sets to run in *Grouped* mode ( ),and increase (all stimulation sets) to the patient preferred level (Figure 7.8).

7. Measurement is only enabled for the applied stimulation set (highlighted in orange. See Figure 7.8). The ECAP measurement and closed-loop settings from the applied stimulation set are used for closed-loop control of all stimulation sets.

    a. To change the applied stimulation set, select the required stimulation set, then choose *Apply FB to this SS* in CLS menu – More (Section 8.4).

8. Enable closed-loop stimulation as per Section 6.13.

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

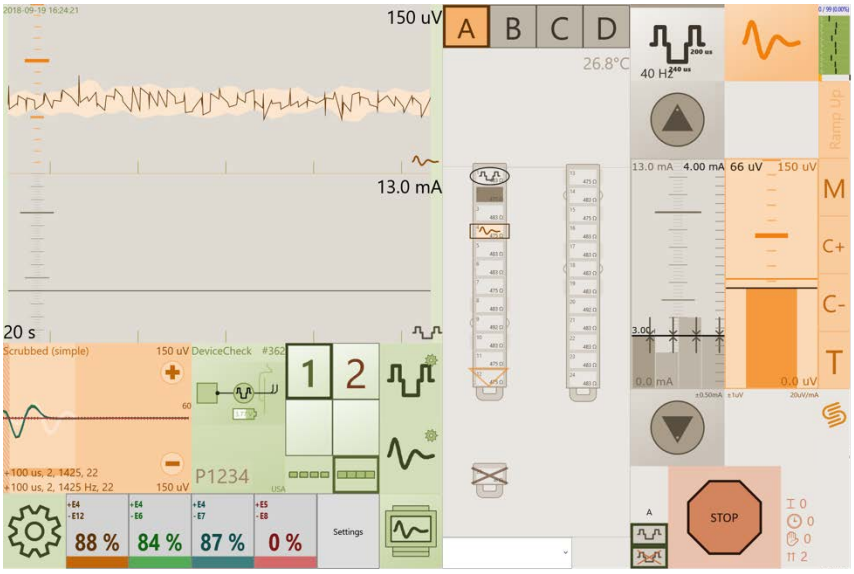


Figure 7.8: A program with 4 Stimulation Sets configured at desired levels. Note that the electrode settings from all Stimulation Sets are visible in the background, while the active set is displayed as normal.

7.5.2 Enable/Disable a stimulation set in a program

To enable/disable a stimulation set in a program:

1. Select the stimulation set you want to enable/disable.

    Note: The applied stimulation set cannot be disabled.

2. Press to enable the stimulation set or to disable it. A disabled stimulation set will have a red diagonal line across it, e.g. .

3. Start stimulation again when the desired changes have been made.

Note: The stimulation sets that are still enabled will continue to increase at the previous ratio (Figure 7.9).

Note: If a stimulation set is disabled ( ) its ratio will be set to 0 and it will need to be reconfigured (refer to Section 7.5.3).

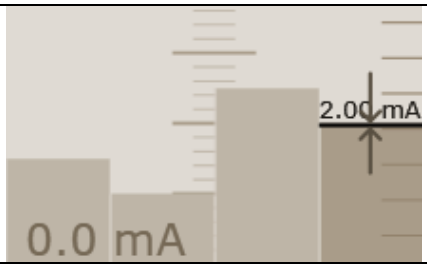
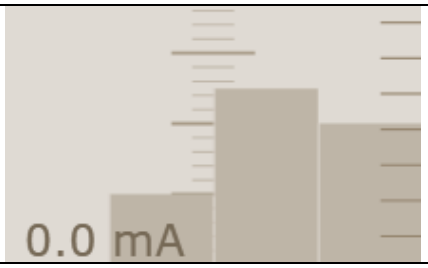
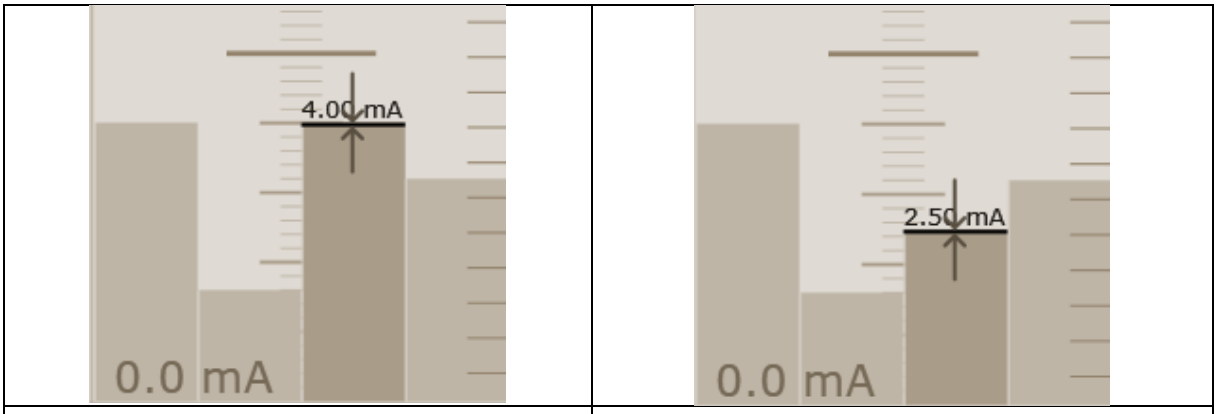
	
All enabled	**Stimulation Set A disabled**

Figure 7.9: (Left) Original current levels with all stimulation sets enabled. (Right) Current levels with stimulation set A disabled.

7.5.3 Changing the ratio between stimulation sets

The ratio between stimulation sets can be changed, even during stimulation (Figure 7.10):

1. Ungroup the stimulation sets ( ).
2. Select the stimulation set and change the current to the new desired level.
3. Group the stimulation sets ( ) and continue stimulation as normal.



Original ratios, stimulation set C selected	Stimulation set C ratio lowered

Figure 7.10: (Left) A program with 4 stimulation sets in Ungrouped mode with stimulation set C selected. (Right) The ratio for stimulation set C has been reduced while the others remain the same.

7.6 Activation plot levels

During programming you may wish to mark activation plot levels. The levels will be indicated by horizontal lines on the intensity bar graphs (Figure 7.11B), and horizontal (ECAP amplitude) and vertical (current) lines on the activation plot (Figure 7.11A).

1. Mark the activation plot levels by touching the following buttons (see Figure 7.11A)
    a. *Threshold* (*T*): ECAP threshold or when the patient first feels a change in sensation (e.g. paresthesia or pain relief).
    b. *Comfort* (*C-* and *C+*): When the patient reports a preferred comfortable sensation, for increasing or decreasing stimulation, respectively.
    c. *Maximum* (*M*): When the patient could tolerate stimulation for no more than approximately one minute.

    Note: When marked, the button becomes a darker orange.
2. 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 (see Section 6.11).
3. 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).

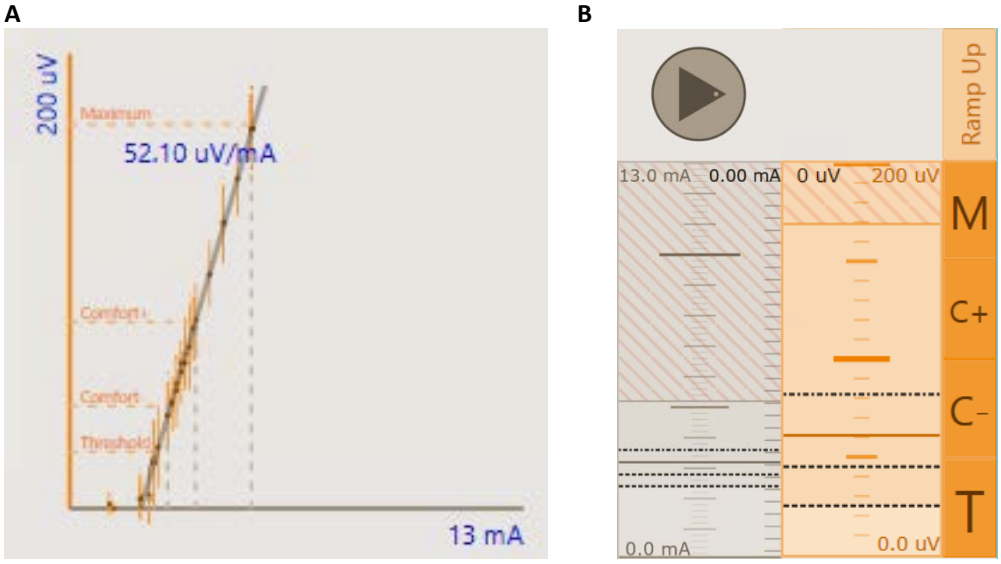


Figure 7.11: A) The activation plot levels displayed on the activation plot. B) Marked levels displayed on the intensity bar graphs (hashed area: above *M;* dotted lines: *C+, C-* and *T*; solid line: level when stimulation was last stopped). The *Ramp Up, M, C+, C-* and *T* buttons are to the right of the bar graphs.

7.6.1 Ramp Up

The stimulation current (closed-loop disabled) or ECAP amplitude target (closed-loop enabled) may be gradually increased automatically (ramped up) by the CPA without touching the *Up* arrow buttons.

1. Touch the *Ramp Up* button (see Figure 7.11B) to gradually increase the stimulation current or target to the next activation plot level or the level when stimulation was last stopped (solid line in Figure 7.11B).

   Note: If stimulation is stopped the *Ramp Up* button will start stimulation and increase to the next marked level. The CPA will only ramp to the level below *M*, but not to the *M* level.

   Note: The maximum rate of the ramp increase may be changed in the settings screen (see Section 8.6)

7.7 Data files

All data downloaded from the stimulator and recorded during a programming session is saved to a clinical data log file on the CI for later review. Files are saved into the Documents folder on the CI in the 'SaludaData' folder, or the 'NonSync' folder if the patient has not consented for data to be transmitted to Saluda Medical (see Section 7.9). The data is organized in folders named with the Patient Zone and Patient ID, and contains folders named with the date, stimulator serial number and Visit Name.

To review the data files refer to the Evoke SCS System Clinical Data Viewer User Manual.

7.7.1 Notes

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

1. Type a text note in the *Notes* field

(see Figure 6.2).
2. Touch the *Enter* button to save the text note with a time-stamp in the clinical data log file, e.g.

. A screenshot of the CPA programming screen is also saved in a 'Screenshot' folder for the relevant visit on the CI.

7.7.2 Patient posture notes

1. Touch the arrow in the *Notes* field to display a list of pre-defined notes (right).
2. Select the required note to save it with a time-stamp in the clinical data log file, e.g.

. A screenshot of the CPA programming screen is also saved in a 'Screenshot' folder for the relevant visit on the CI.

7.7.3 Screenshots

1. Touch the *Communication Quality Indicator* icon (see Section 8.7.4) to save a screenshot of the CPA programming screen.
2. The icon will briefly change its appearance to show a camera graphic to indicate that the screenshot was saved.
3. The screenshot is saved in a 'Screenshot' folder for the relevant visit on the CI.

7.8 Neurophysiological measurements

The CPA can be used with the eCLS/CLS to measure the neurophysiological characteristics of the patient's spinal cord as well as to test the vertical alignment of the two implanted leads.

1. Touch the *CLS* icon

, then touch the *More…* field and select *Show Neurophysiological Measurements*. The neurophysiological measurement menu will appear adjacent to the navigation menu icon (Figure 7.12).

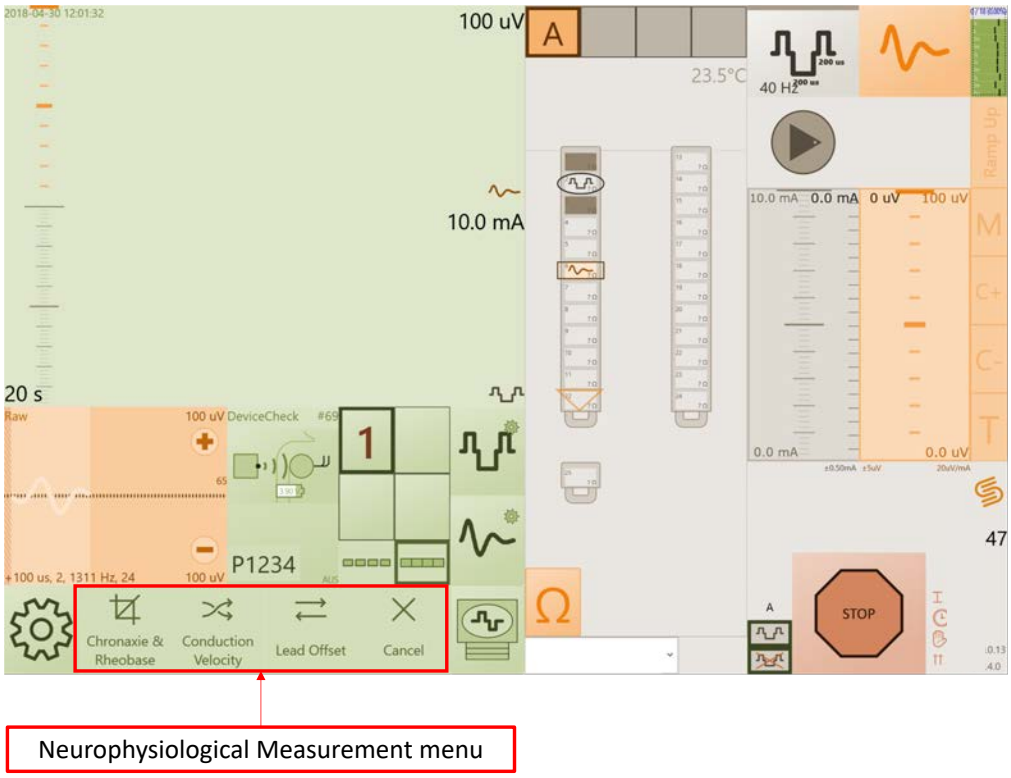


Figure 7.12 Location of controls to initiate neurophysiological measurements.

7.8.1 Neurophysiological measurement menu

Chronaxie & Rheobase	**Perform a Chronaxie and Rheobase Measurement**	Collect data to estimate the chronaxie and rheobase of the stimulated neurons. See Section 7.8.2.
Conduction Velocity	**Perform a Conduction Velocity Measurement**	Collect data to estimate the conduction velocity of evoked neural responses in the dorsal spinal cord. See Section 7.8.3.
Lead Offset	**Perform a Lead Offset Measurement**	Perform a lead offset measurement to estimate the vertical alignment of two implanted leads. See Section 7.8.4.
Cancel	**Cancel**	Close neurophysiological measurement menu.

7.8.2 Chronaxie and rheobase measurement

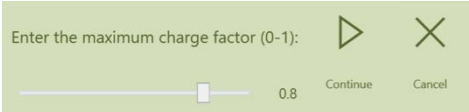
Collect data to estimate the chronaxie and rheobase of the stimulated neurons**.** The chronaxie and cheobase measurement involves automatically increasing then decreasing current at different pulse widths. Stimulation may be stopped at any time with the Stop button

.

To perform a chronaxie and rheobase measurement:

1. Ensure the electrode configuration has been optimized for ECAP measurement.
2. Touch *Chronaxie & Rheobase*

from the neurophysiological measurement menu.
3. Use the sliding scale to input the maximum charge factor (default is 0.8, Section 20.4 for definition) and touch *Continue*.



see

4. Use the sliding scale to input the current ramp speed (default is 20 steps) and touch *Continue*.

5. Touch *Yes* if you wish to set the program parameters to the chronaxie and rheobase measurement defaults.
6. Touch *No* if you wish to use the existing program parameters.

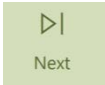
   Note: The pulse width must be greater than 240µs.
7. Start stimulation with closed-loop disabled and then touch *Continue*.
8. Ask the patient to remain still for the duration of the test and to inform you if the stimulation becomes too strong. Inform the patient that the stimulation current and pulse width will be automatically adjusted by the CPA during the measurement.
9. With the patient ready to begin, increase the current until the patient reports that it is at the maximum level (can tolerate for approximately 1 minute).
10. Touch *Continue* to begin data collection.

    Note: Begin the test immediately after increasing the stimulation current to maximum (Step 9) in order to minimize patient discomfort.
11. Touch the *Pause*

button, at any time, to stop the current changing. This may be required if the patient does not want the stimulation to increase any further. The current will then remain constant until you press one of the following buttons:

    a. Touch *Resume*

to continue changing current in the same direction.

b. If current was increasing touch *Next* 

to start the current decreasing.

c. Touch *Cancel*

to turn stimulation off and stop the chronaxie and rheobase measurement.

12. After completion of the measurement, the stimulation settings will return to their state prior to the initiation of the measurement.
13. Touch *Continue* to return to the neurophysiological measurement menu
14. Touch the *Cancel* button to close the neurophysiological measurements menu.
15. Use the CDV to calculate chronaxie and rheobase using the data that was collected. Refer to Evoke SCS System Clinical Data Viewer User Manual for instructions.

7.8.3 Conduction velocity measurement

Collect data to estimate the velocity at which elicited neural responses travel up or down the spinal cord. The CPA automatically moves the measurement and reference electrode (if applicable) at a fixed current level.

To perform a conduction velocity measurement:

1. Choose the stimulation electrode configuration and settings.
2. Touch *Conduction Velocity*

from the neurophysiological measurement menu.
3. Touch *Fixed Reference*

for recording configurations in which the reference electrode
is to remain fixed.
4. Touch *Fixed Distance*

for recording configurations in which the reference electrode
is to remain a fixed distance from the measurement electrode.
5. Set the initial measurement electrode positions (see Figure 7.13):
   a. The measurement electrode is usually placed near the stimulation and return 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).

   b. 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.

c. For fixed distance recordings, the reference electrode is typically placed 2 or 3 electrodes from the measurement electrode.

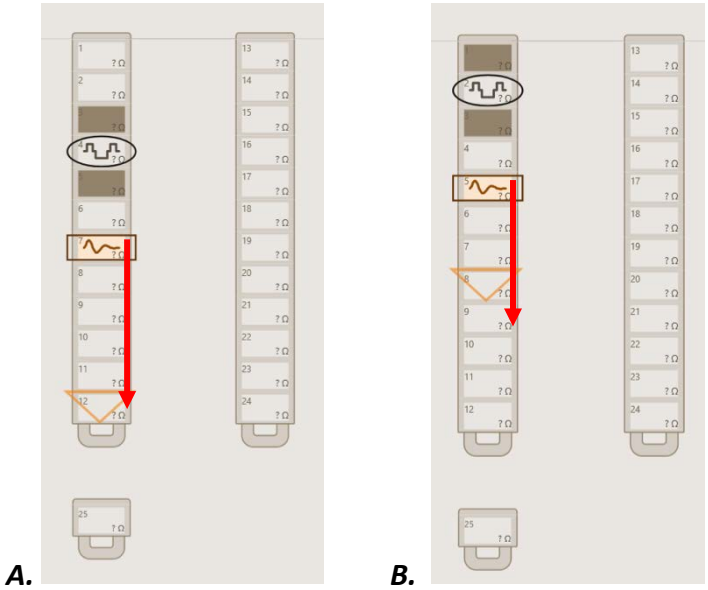


Figure 7.13 Example starting electrode positions for:
***A.* Fixed reference recordings; *B.* Fixed distance recordings.**

6. Touch Continue.
7. Touch the *direction* icon for the direction that the measurement electrode should move.
8. Start stimulation with closed-loop disabled and touch *Continue*.
9. Ask the patient to remain still for the duration of the test, then increase the current until the patient reports that the stimulation is at the maximum level (M; can tolerate for approximately 1 minute). Then reduce the current until the patient reports it has returned to a comfortable level (C+).
10. Touch *Continue* to begin data collection.
11. After completion of the measurements, reset the electrode configuration to the patient's settings.
12. Touch the *Cancel* button to close the neurophysiological measurements menu.
13. Use the CDV to calculate conduction velocity using the data that was collected. Refer to Evoke SCS System Clinical Data Viewer User Manual for instructions.

7.8.4 Lead offset measurement

Collect data to automatically estimate the vertical alignment of the implanted leads. The lead offset measurement will report the vertical distance in electrode spacings and millimeters that the electrode leads are mismatched.

To estimate the lead offset:

1. Touch *Lead Offset*

from the neurophysiological measurement menu.

   Note: Ensure that only the applied stimulation set is enabled before continuing (see Section 7.5). The lead offset test will save the stimulation set parameters before the test and restore them after the test.

2. Touch *Start*

to start the lead offset 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

to stop the stimulation at any time and cancel the lead offset test.

3. Wait for the measurements to complete. The test will cycle through up to 6 stimulation locations, until the lead offset can be confidently calculated.

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

. The results for stimulation locations with completed measurements will be plotted (see Figure 7.14), but the lead offset result will be invalid.

4. After completion, the results of all lead offset measurements will be plotted (Figure 7.14) and the lead offset distance displayed.

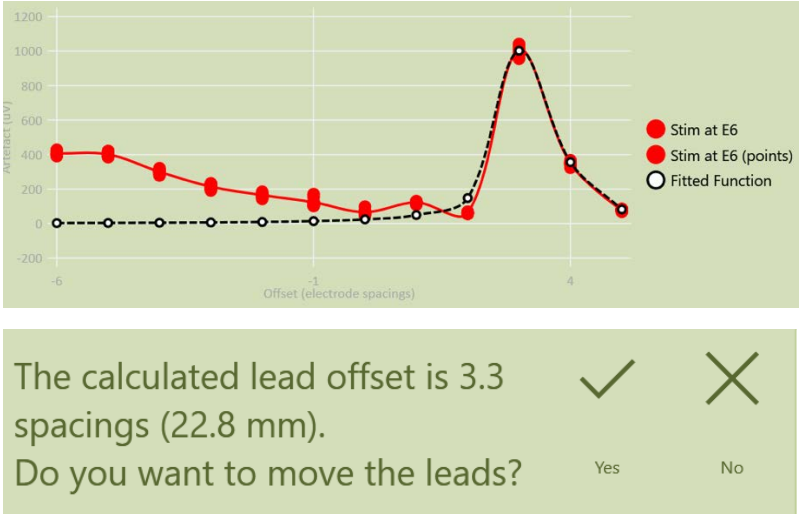


Figure 7.14 Lead offset measurement plot and lead offset distance display. The peak of the plot indicates the lead offset distance (electrode spacings).

5. If the lead offset measurement is valid, touch *Yes* to move the leads based on the measured offset, otherwise touch *No* to continue without adjusting the lead display. The stimulation set parameters will be restored.

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.

6. If the lead offset measurement is invalid, touch *OK* to restore the stimulation set parameters.
7. Touch *Continue* to end the lead offset test.
8. Touch the *Cancel* button to close the neurophysiological measurements menu.

7.9 Additional impedance measurements

The CPA can be used for measuring the impedance between contacts:

1. Touch the *CLS* icon , then touch the *More…* field and select *Measure Impedances*. Two options will be available (see Section 8.4):
   - **All impedances:** Measures the impedance between each pair of electrodes (i.e. E1 to E2, E1 to E3 … E1 to E24, E2 to E3, etc.)
     Note: This will take approximately 8 minutes.
   - **Load from file:** Measure the impedances between electrodes specified in a '.csv' file.
     Note: The file will be provided by Saluda Medical Field Clinical Engineer (FCE) if required.

   Note: The impedance measurement can be cancelled by pressing the 'Cancel' button below the CLS Menu once measurement has started. This will save the measurements collected so far.

The impedance measurements will be written to a '.JSON' file and saved in the 'Logs' folder for the corresponding patient visit (see Section 7.7 for more details).

7.10 Patient Survey

Depending on the Patient Zone, a survey may be completed to document the patient's demographics, pain history, and experience with SCS.

Note: The questions in the survey may vary between Patient Zones.

1. Touch the navigation menu icon and then touch *Survey*.
2. The patient must give consent for the clinician to collect the survey information and for the information to be backed-up remotely on Saluda Medical servers.
3. Read the consent language to the patient and record the answer on the survey page (Figure 7.15)

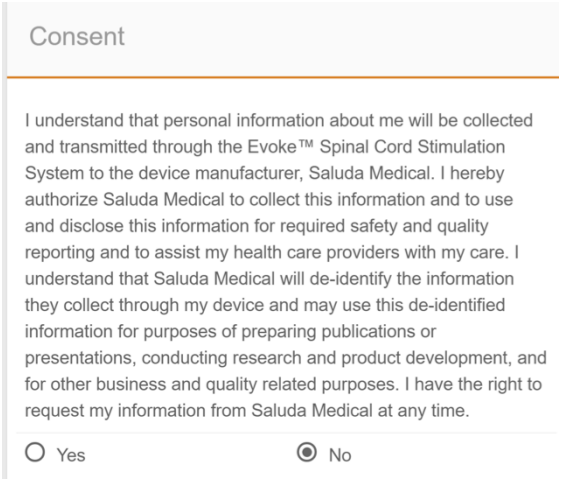


Figure 7.15: Example Consent question.

Note: The Patient ID on the CLS Programming page will be in green text if the consent answer is Yes (e.g. P1234)and orange if the consent answer is No (e.g. P1234).

4. The session list displays all the surveys that have been created (Figure 7.16).

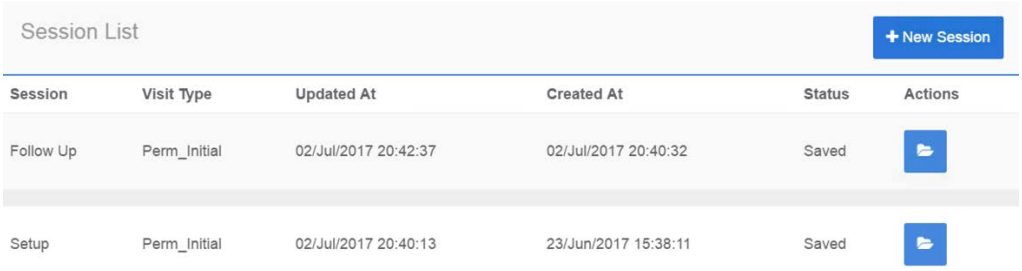


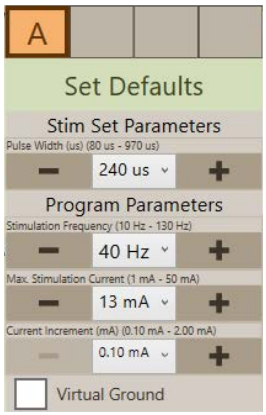
Figure 7.16: Survey session list.

7.10.1 Start Survey

1. Touch the *+ New Session* button to create a new survey (Figure 7.16).
   a. For a new patient a Setup survey will be created.
   b. For an existing patient a Follow Up survey will be created.
2. Touch the *open* icon to start the created survey or you may *delete* an unsaved survey.
3. Complete the survey questions and then touch the *Save and Close* button to save the survey data to the stimulator. Otherwise touch the *Back to Sessions* button to exit the survey without saving.
4. Touch the *open* icon to open a survey to correct any information.

8 Clinical Interface – Settings guide

8.1 Stimulation settings menu

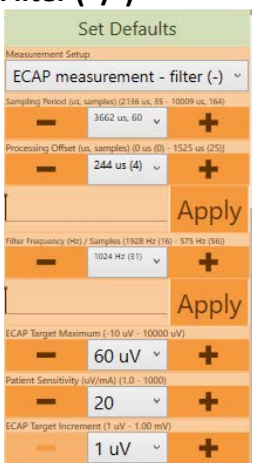


Stimulation Set selection	Stimulation set slots, labeled A, B, C or D. Empty slots represent unused stimulation sets.
Stim Set Parameters	
Set Defaults	Set stimulation settings to default values for the selected stimulation set
Pulse Width	20 – 1000 µs
Program Parameters	
Stimulation Frequency (Hz)	10 – 1500 Hz closed-loop disabled 10 – 250 Hz closed-loop enabled
Maximum stimulation current	1 – 50 mA
Current Increment	0.05 mA – 4.0 mA (depending on the electrode setup)
Virtual Ground **- ClearCAP feature**	Enable (checked) / Disable (unchecked) Virtual Ground stimulation (ClearCAP). Sets the Reference electrode as an input for Virtual Ground (ClearCAP) (see Section 7.2).

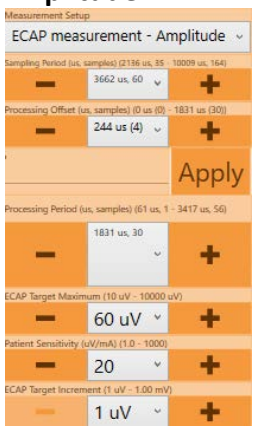
Note: *Stim Set Parameters* only apply to the selected stimulation set. *Program Parameters* apply to all stimulation sets. The available range of each setting is shown.

8.2 Measurement and feedback settings menu

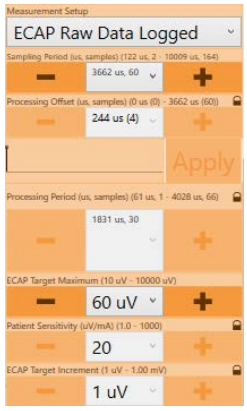
Filter (+/-)



Amplitude



Raw Data



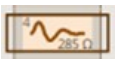
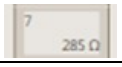
Set Defaults	Set Measurement and Feedback Settings to default values
Measurement Setup *	Raw data, Filter (+), Filter (-), Amplitude **Note:** For Raw data, Closed-loop is disabled and the settings for Processing Offset, Processing Period, Patient Sensitivity, and ECAP Target Increment are disabled.
Sampling Period	122 – 10009 µs (2 – 164 samples)
Processing Offset	0 – 3662 µs (0 – 60 samples)
Processing Offset plot	ECAP amplitude vs. processing offset. Open circle – recommended offset (peak of plot); black line – offset used. Press *Apply* to use recommended offset.
Filter Frequency (Filter +/- mode only)	496 – 1928 Hz (65 – 16 samples)
Filter Frequency plot (Filter +/- mode only)	ECAP amplitude vs. filter samples. Open circle – recommended samples (peak of plot); black line – samples used. Press *Apply* to use recommended filter samples.
Processing Period (Amplitude mode only)	61 – 4028 µs (1 – 66 samples)
ECAP Target Maximum	-900 – 1000 µV
Patient Sensitivity	14 – 1000 µV/mA
ECAP Target increment	1 – 1000 µV

Note: The valid 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.

8.3 Electrode selection modes

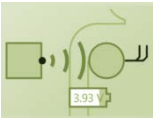
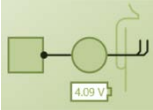
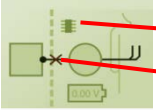
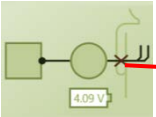
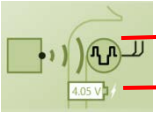
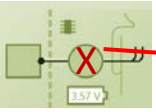
You can configure electrodes automatically or manually by touching the *Electrode Selection Mode* icon when stimulation is turned off. The selection mode toggles between:

	Automatic electrode selection	You select the stimulation electrode and all other electrodes are chosen automatically: • 1st touch – Tripolar • 2nd touch – Bipolar • 3rd touch – Tripolar on each lead • 4th touch – Bipolar on each lead • 5th touch – No electrodes
	Measurement electrode selection	You select the measurement electrode (ECAP amplifier positive input) required and all the other electrodes remain the same. **Note:** Can be changed during stimulation if closed-loop is disabled. *
	Reference electrode selection	You select the reference electrode (ECAP amplifier negative input) required and all the other electrodes remain the same. **Note:** Can be changed during stimulation if closed-loop is disabled. *
	Manual electrode selection	You select the electrode you wish to change and the electrode will toggle between: Stimulation Stimulation return  Measurement – ECAP amplifier positive (+) input Reference – ECAP amplifier negative (-) input  Not selected

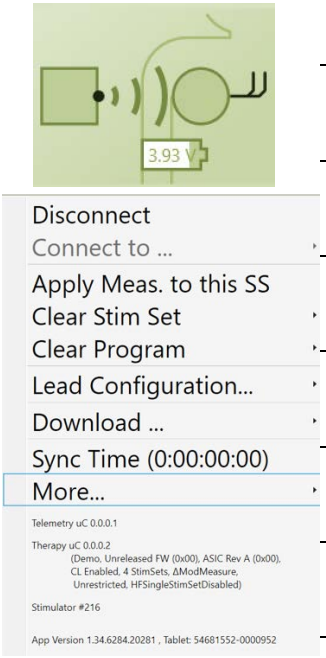
*** Note:** The measurement and reference electrodes may not be moved to be adjacent to the stimulation or return electrodes.

8.4 CLS menu

The *CLS* icon displays the status of the stimulator.

	Connected to CLS
	Connected to eCLS
	Demo stimulator Stimulator is disconnected
	CLS time is not synchronized CST is disconnected Stimulator battery voltage indicator
	Electrode disconnected
	Stimulation is on CLS battery is being charged
	Safe Mode error

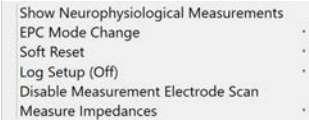
Touch the *CLS* icon for additional CLS and eCLS functions.



Disconnect	Disconnect CPA from stimulator.
Connect to … Implant	Search and connect CPA to stimulator.
Connect to … Demo	Run in Demonstration mode. Normal operation connected to a simulated (demo) stimulator.
Apply Meas. to this SS	Apply measurement to the selected stimulation set.
Clear Stim Set	Clear the selected stimulation set from the program.
Clear Program	Clear the selected program from the stimulator.
Lead Configuration…	Switch between different lead types.
Download… Usage Logs	Download usage logs from stimulator.
Download … Therapy Logs	Download therapy logs from stimulator.
Download… Error Logs	Download error logs from stimulator.
Sync Time	Synchronize stimulator time with CI.
More…	Access next menu window.
Telemetry uC	The telemetry version on CLS or eCLS.
Therapy uC	The therapy version on CLS or eCLS.
Stimulator #	The eCLS or CLS ID number.
App Version	The version of the CPA.

Touch the 'More…' field for the next menu.

Show Neurophysiological Measurements	Show the neurophysiological measurements menu.



EPC Mode Change	Enable or disable the ability use the EPC to enable/disable CL stimulation. When EPC Mode Change is *Enabled,* CL can be enabled/disabled from the EPC. When EPC Mode Change is *Disabled,* CL cannnot be enabled/disabled from the EPC. To indicate this, a padlock symbol is displayed over the mode not in use. *CL cannot be disabled with EPC* *CL cannot be enabled with EPC*
Soft Reset	Reset stimulator, clear Safe Mode errors, clear programs and reconnect
Log Setup	Set up therapy log settings: Size: Normal (1.5 MB) or Research (13 MB) Duration: 1 day to 1 year
Disable / Enable Measurement Electrode Scan	*Disable* or *Enable* the measurement electrode scan for the duration of the programming session.
Measure Impedances	**All impedances:** Measure impedance between all electrode pairs. **From file:** Load file to measure specific impedances.

8.5 Navigation menu

Touch the navigation menu icon for additional CPA functions.

←	Close navigation menu
Quit	Close CPA – stimulation will continue if on
Survey	Go to the patient survey screen (see Section 7.9)
Settings	Go to the settings screen (see Section 8.6)
Programming	Go to the CLS programming screen.

8.6 Settings screen

Touch the navigation menu icon and choose *Settings* for additional settings (Figure 8.1).

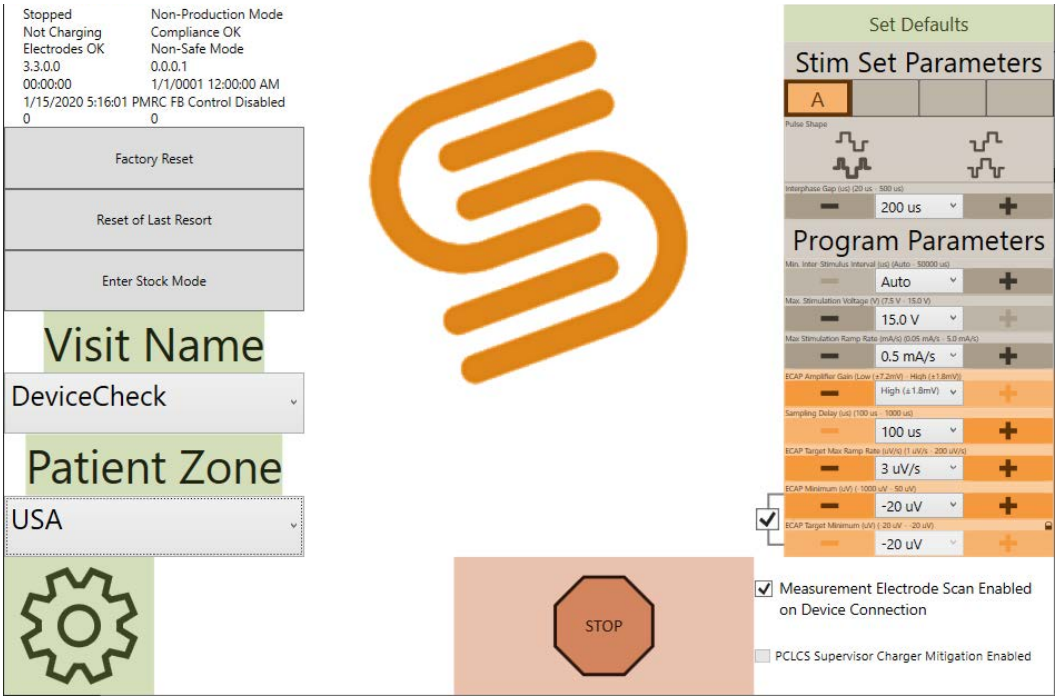
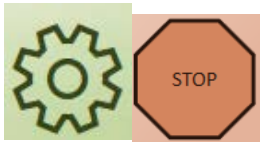
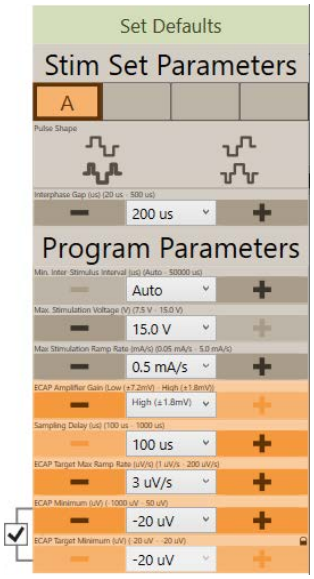


Figure 8.1: Settings screen.

	**Navigation Menu**	Open the navigation menu.
	Stop	Stop stimulation
	Engineering Information	Used by Saluda Medical staff to obtain device related information
	Factory Reset	Restore devices to default factory settings. For use by Saluda Medical Field Clinical Engineer (FCE).
	Reset of Last Resort	For use by FCE.
	Enter Stock Mode	Stop all CLS functions to conserve battery. Use the Charger to leave stock mode.
	Visit Name	Set label name for programming visit
	Patient Zone	Set the region or zone for the patient
	**Stim Set Parameters**	
	Set Defaults	Set settings menu values to defaults for the selected stimulation set
	Stimulation Set selection	Stimulation set slots, labeled A, B, C or D. Empty slots represent unused stimulation sets
	Pulse Shape	Biphasic - Positive first, Negative first Triphasic - Positive first, Negative first
	Interphase Gap	20 – 500 µs
	Program Parameters	
	Min Inter-Stimulus Interval	Interval of stimulation set pulses Auto (minimum permitted ISI), 1400 – 50000 µs
	Max Stimulation Voltage	7.5 – 15 V (ClearCAP disabled) 15 V only (ClearCAP enabled)
	Max Stimulation Ramp Rate	Only applies when connected to CPA. 0.05 – 5.0 mA/s
	ECAP Amplifier Setting	ECAP amplifier gain setting. High (± 1.8 mV), Low (± 7.2 mV)
	Sampling Delay	100 – 1000 µs

	ECAP Target Max Ramp Rate	Only applies when connected to CPA. 1 – 200 µV/s
	ECAP Minimum	Minimum ECAP amplitude recorded by the stimulator (-1000 – 1000 µV)
	ECAP Target Minimum ***Checkbox***	Minimum ECAP Target that can be set with the CPA or EPC (-1000 – 1000 µV). Link to 'ECAP Minimum' value (checked, default) or not linked (unchecked).
	Measurement Electrodes Scan Enabled on Device Connection	Disable (not checked) or enable (checked) the Measurement Electrode Scan on connection to a device.
☑ Measurement Electrode Scan Enabled on Device Connection ☐ PCLCS Supervisor Charger Mitigation Enabled	**PCLCS Supervisor Charger Mitigation Enabled**	'PCLCS Supervisor' disables CL during CLS charging. When charging is started with stimulation on, if the mitigation is: Enabled (checked), then stimulation continues with CL disabled. Disabled (unchecked), then stimulation stops.

Note: *Stim Set Parameters* only apply to the selected stimulation set. *Program Parameters* apply to all stimulation sets. The available range of each setting is shown.

8.7 Alert and error display

Alerts and errors will be displayed over the ECAP amplitude and current rolling plot (Figure 8.2). A count of the alerts from the Error Log are also displayed to the right of the *Stop* button (see Table 8.1 for more information regarding the symbols).

For more information regarding how the stimulator responds to alerts and errors see Section 12.

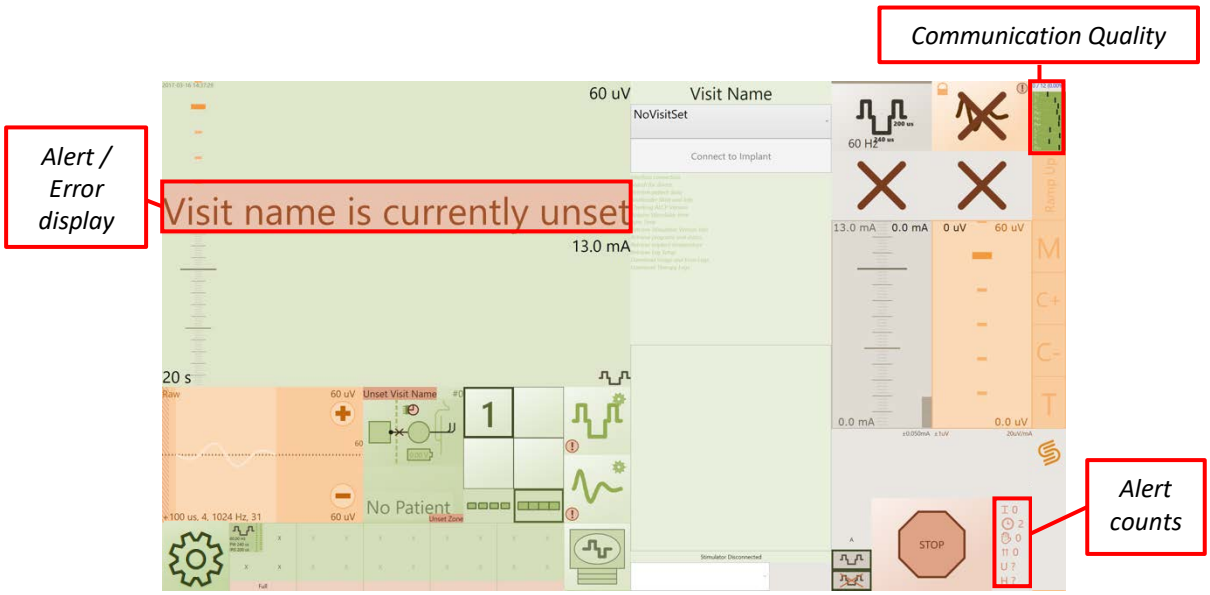


Figure 8.2: Alert and error display and alert counts on the programming screen.

Table 8.1: Alert count symbol information. Note that a '?' means the corresponding log was not downloaded, or that an issue occurred during download. Stop stimulation and download the log again.

Symbol and count	Description
I 0	Clipping count
0	Reference clock error count
2	Magnet stop count (see Evoke SCS System User Manual)
1	Current at maximum count
U ?	If present, then Usage Log did not download or there was an error
H ?	If present, then Therapy Log did not download or there was an error

8.7.1 Clipping alert

Clipping alerts during stimulation are displayed on the ECAP display (Figure 8.3).

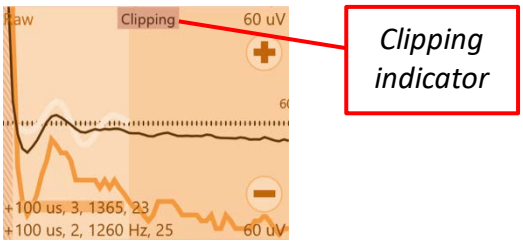


Figure 8.3: Clipping indicator.

8.7.2 Out-of-compliance alert

Out-of-compliance (OOC) alerts are displayed on the stimulation current control (Figure 8.4).

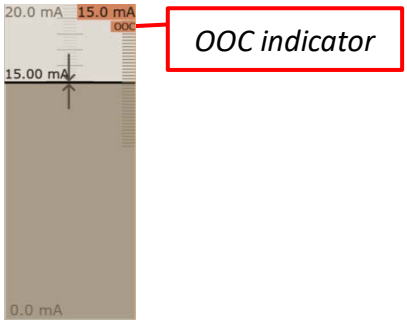
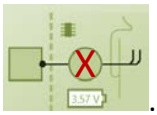


Figure 8.4: Out-of-compliance indicator.

8.7.3 Safe Mode errors

A red cross in the CLS icon indicates a Safe Mode error  . 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 EPC and Charger (see Evoke SCS System User Manual). If a Safe Mode error is encountered:

1. Use the CPA to reset the CLS or eCLS out of Safe Mode (see *Soft Reset* in Section 8.4).
2. Contact Saluda Medical to report the occurrence of the error code displayed.

8.7.4 Communication Quality Indicator

The quality of the radio communication between the CST and the stimulator is indicated on the communication quality indicator for use by the Saluda Medical representative. The indicator shows if each command is successful or fails, the time between commands sent, and the % of commands that fail (Figure 8.5).

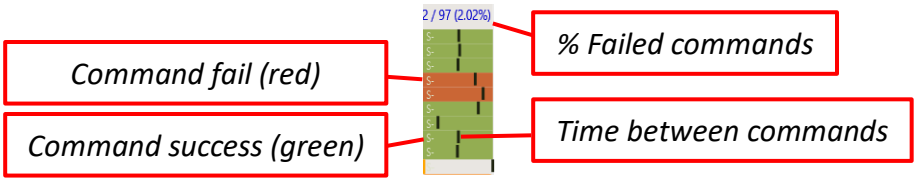


Figure 8.5: Communication Quality Indicator.

If there are frequent failed commands and/or variable time between commands, move the CST closer to the stimulator to improve communication.

> **Note:** Touch the *Communication Quality Indicator* icon to save a screenshot of the CPA screen (see Section 7.7.1).

9 Intra-operative programming with the CI

> **Note**: The Evoke SCS System Surgical Guide provides specific information about surgical procedures and necessary connections between leads/extensions/Intraoperative Cable /CLS/eCLS as required for the various procedures.
>
> **Note**: Neither the CI or the CST are supplied sterile and should not be used inside the sterile field; see Evoke SCS System Surgical Guide for details.

Following lead placement based on required anatomical location, the surgeon connects the leads to the intraoperative cable inside the sterile field (see Evoke SCS System Surgical Guide for details). The surgeon passes the proximal end of the intraoperative cable out of the sterile field to the programming clinician.

9.1 Connect the intraoperative cable to the eCLS

This section is to be completed by the programming clinician outside of the sterile field.

1. Connect the proximal end of the intraoperative cable to the eCLS (refer to Figure 9.1).

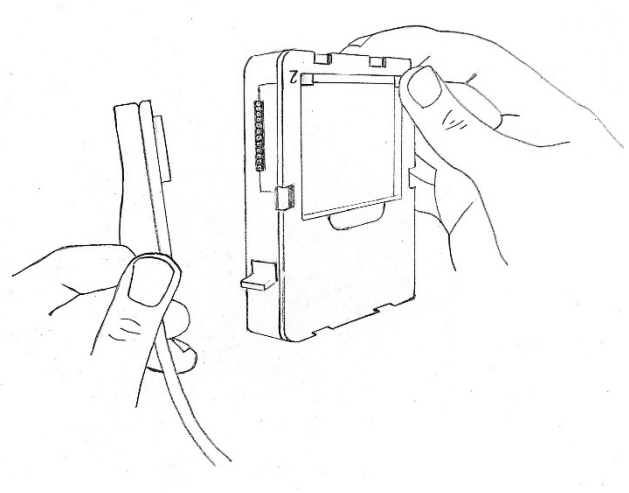


Figure 9.1: Connect the proximal end of the intraoperative cable to the eCLS. Port 2 (electrodes 13–24) is shown here. Port 1 (electrodes 1-12) is on the opposite side of the eCLS.

9.2 Confirm optimal lead placement

Physicians may have a preference on the method to confirm optimal lead placement in the operating room. Lead position may be confirmed anatomically, incorporating ECAP measurement, and/or through paresthesia mapping using intraoperative patient feedback. Physicians may use one or more of the following methods to confirm medio-lateral lead location, dermatomal coverage, ability to measure ECAPs, and/or paresthesia coverage of the pain areas:

- If confirmation of optimal lead placement will be based on ECAP measurement, go to Section 9.2.1.
- If paresthesia mapping is to be performed, go to Section 9.2.2.

9.2.1 ECAP measurement

This section is to be completed by the programming clinician outside of the sterile field. Refer to Section 6 for detailed programming instructions.

1. Connect the CI to the eCLS.
2. Check electrode impedances using the CPA to ensure the leads are connected properly.
    - If any electrode has an impedance measurement that is greater than 4000 Ω, check all the connections.
    - Check impedances after each reconnection
3. Select the stimulation and measurement electrodes and settings.
4. Verify that an ECAP can be measured by stimulating, for example, at the top and bottom of the lead
    - If the ECAP measured is not satisfactory, change the electrodes, stimulation or measurement settings using the CPA or ask the surgeon to move the

percutaneous lead(s) to a new position.

- Verify ECAP measurement after changing settings or moving the percutaneous lead(s).

5. When satisfied with the lead placement, turn stimulation off and disconnect the eCLS from the intraoperative cable.
6. The surgeon then disconnects the intraoperative cable from the lead.

9.2.2 Paresthesia mapping

This section is to be completed by the programming clinician outside of the sterile field. Refer to Section 6 for detailed programming instructions.

1. Connect the CI to the eCLS.
2. Check electrode impedances using the CPA to ensure the leads are connected properly (see Section 6.5)
    - If any electrode has an impedance measurement that is greater than 4000 Ω, check all the connections.
    - Check impedances after each reconnection.
3. Select the stimulation and measurement electrodes and settings.
4. Increase stimulation current until the patient reports a strong but comfortable level of paresthesia (tingling).
5. The patient should report paresthesia coverage of the dermatomes that align with their pain area(s).
    - If paresthesia coverage is not satisfactory, change the electrode and stimulation settings using the CI or ask the surgeon to move the percutaneous lead(s) to a new position.
6. Retest paresthesia coverage after changing settings or moving the percutaneous lead(s).
7. When satisfied with the lead placement, turn stimulation off and disconnect the eCLS from the intraoperative cable.
8. The surgeon then disconnects the intraoperative cable from the lead.

9.3 Confirm CLS connection

This task is only performed if a CLS is being implanted. The surgeon creates a pocket for the CLS and tunnels the leads to the pocket. The surgeon inserts the proximal connector end of the lead into the ports in the header of the CLS and places the CLS partially into the CLS pocket.

Programming clinician tasks:

1. Connect the CI to the CLS via the CST (see Section 6.1).
2. Check electrode impedances using the CPA to ensure the proximal connectors are connected properly (see Section 6.5).

- If any electrode has an impedance measurement that is greater than 4000Ω, check all the connections.
- Check impedances after each reconnection.

3. The surgeon tightens the set-screw on the CLS header when satisfied that there is a proper connection.
    - Always check impedances before closing surgical incisions.

10 Post-operative programming procedures

The stimulator (eCLS or CLS) can be programmed when the patient has recovered sufficiently to interact with the programming clinician.

If the patient has externalized leads or lead extensions for the purpose of a temporary trial, refer to Section 11 below to prepare the eCLS for the trial stimulation period.

Programming should be conducted as described in Section 6.

11 Prepare the eCLS for the trial stimulation period

If the patient has externalized leads or lead extensions for the purpose of a temporary trial, the externalized leads or extensions will need to be connected to the lead adapter (see Section 11.1), which in turn will need to be connected to the eCLS (see Section 11.2). The eCLS with a fully charged battery (see Section 11.4) is then placed into the eCLS case (see Section 11.3) and secured for the trial stimulation period (see Section 11.5).

11.1 Connect the lead or lead extension to the lead adapter

1. Place the tip of the proximal connector end of the lead into the end of the lead adapter slot (Figure 11.1).

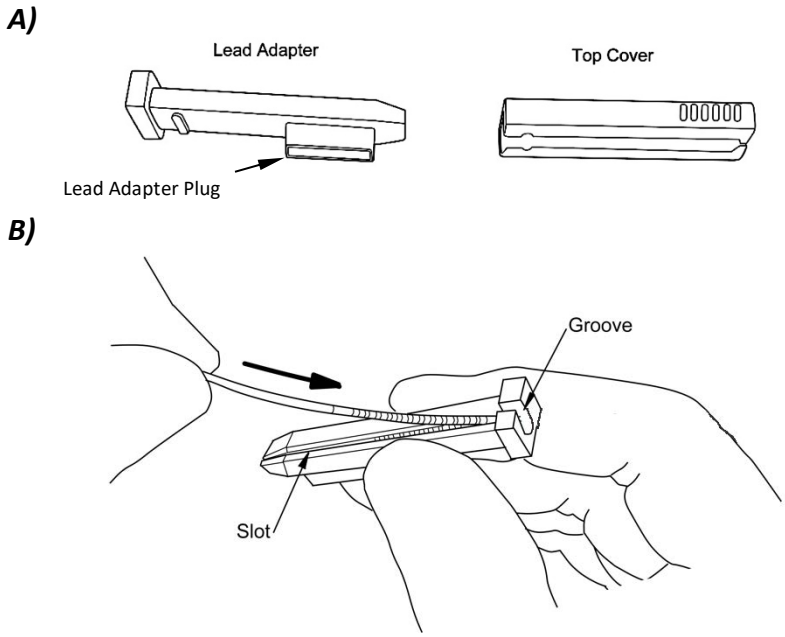


Figure 11.1: A) The lead adapter. B) Placing the tip of the proximal connector into the lead adapter slot.

2. Push the lead down into the slot completely using your finger (Figure 11.2), so that the lead is flush with the top of the slot. The lead should not move when fully pushed into the slot. After the lead is in the slot, press down again along its length to ensure it is secure in the slot.

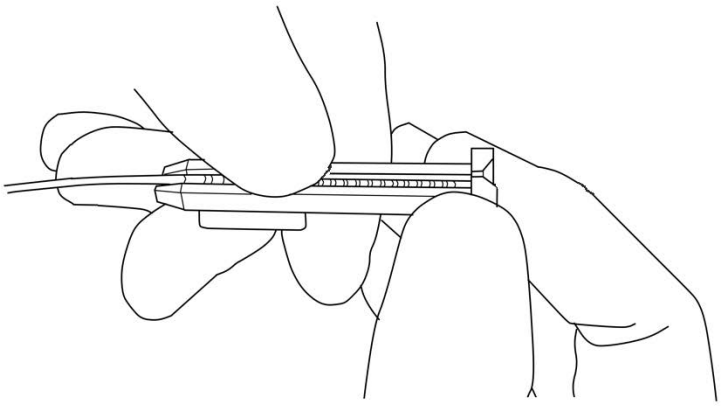


Figure 11.2: Pushing lead into lead adapter slot.

3. Place the top cover of the lead adapter over the lead, with the open side of the top cover aligned with the lead adapter plug. Slide the top cover all the way onto the lead adapter until the notch on the top cover clips into place (refer to Figure 11.3).

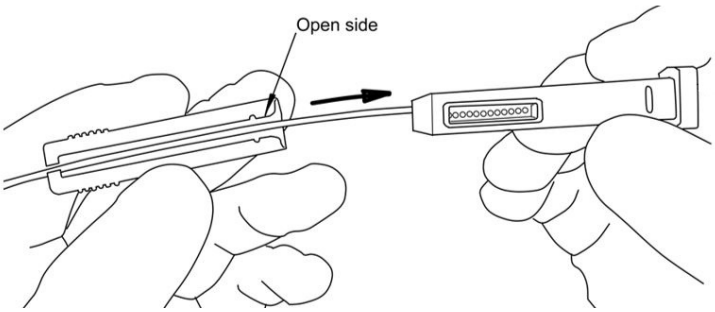


Figure 11.3: Placing the top cover over the lead and sliding onto lead adapter until it clips into place.

11.2 Connect the lead adapter to the eCLS

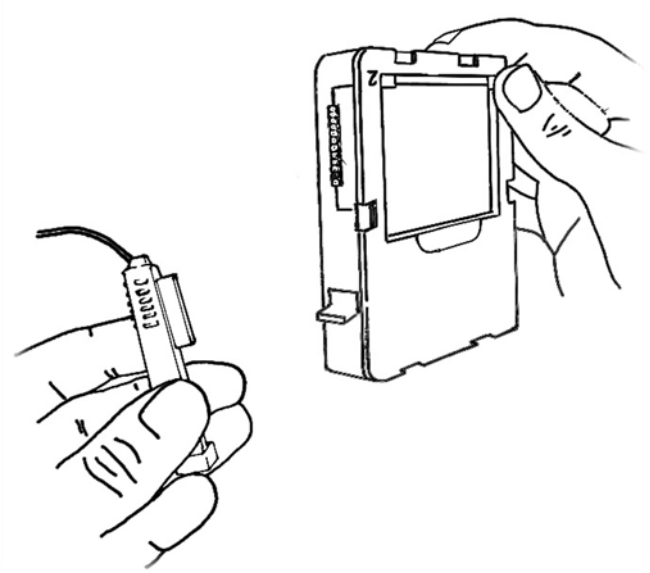


Figure 11.4: Connecting the lead adapter to the eCLS. Port 2 (electrodes 13–24) is shown here. Port 1 (electrodes 1-12) is on the opposite side of the eCLS.

1. Line up the end of the lead adapter plug with the socket on the eCLS port to ensure the connector pins do not get bent (Figure 11.4). Push the lead adapter plug into the eCLS until it clips into place.
    a. The eCLS ports are labelled ‘1’ on one side for electrodes 1-12 and ‘2’ on the other side for electrodes 13-24.

    Note: If you are reconnecting leads to an eCLS that has already been programmed, ensure that the lead and lead adapter are reinserted into the same ports as used during previous programming sessions.

2. To connect a second lead to the lead adapter, repeat the steps in Sections 11 and 11.2.

11.3 Place the eCLS into the case

1. Ensure that a fully charged battery is inserted in the eCLS (see Section 11.4; Figure 11.5).
2. Open the eCLS case with the lead exits pointing up. Place the eCLS into the orange seal side of the case, with the eCLS battery facing up and the leads pointing up over the lead exits (see Figure 11.5).
3. Place the leads into the slots in the seal at the lead exits.

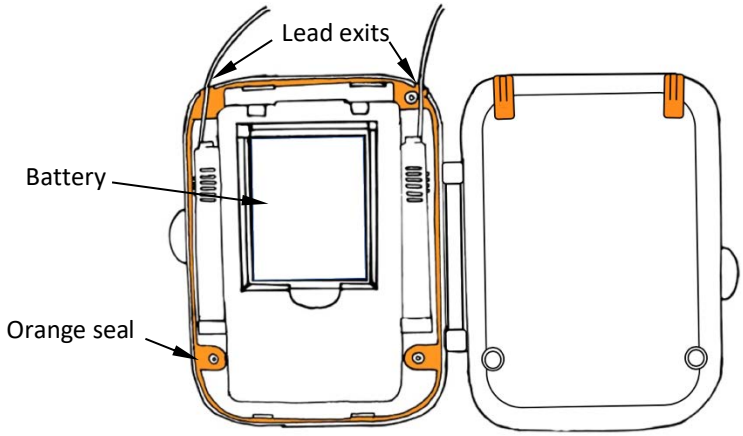


Figure 11.5: Place the eCLS with leads connected into the eCLS Case.

4. Close the eCLS case by folding the case shut until it snaps closed (Figure 11.6). Ensure that the leads do not move from the slots in the seal. The leads may be damaged when the case is closed if they are not in the slots in the seal at the lead exits.

Figure 11.6 eCLS with two leads connected enclosed in case.

5. After the eCLS is connected and in the eCLS case it may be programmed (see Section 6) and set up for the patient to wear for the trial stimulation period (see Section 11.5).

11.4 Charge the eCLS battery

1. Before the patient goes home with an eCLS, a fully charged eCLS battery should be in

place (see Figure 11.5).

2. Check the battery voltage with the CPA (see Section 6.3).
3. To charge the eCLS battery:
    a. Disconnect the intraoperative cables or lead adapters from the eCLS.
    b. Remove the battery from the eCLS.
    c. Charge the battery using the supplied eCLS battery charger.
4. Place the charged battery into the eCLS
5. Connect intraoperative cables or lead adapters to the eCLS.

11.5 Secure the eCLS for the trial stimulation period

1. The eCLS may be worn by the patient for the duration of the trial stimulation period in either of two ways:
    a. In a pouch (see the Accessory Belt section in the Evoke SCS System User Manual), or
    b. Placed on a dressing and taped to the skin by the clinician.
2. The eCLS and leads remain connected inside the eCLS case during the trial stimulation period. If the leads become disconnected from the eCLS or the patient needs to disconnect the eCLS for any reason the patient should return to the clinic.

12 Behaviour of the stimulator when alerts occur

Refer to Section 8.7 for alert and error display on the CPA.

12.1 Out of compliance

Out of compliance (OOC) occurs when the voltage requirement exceeds the maximum stimulation voltage (see Section 8.6). 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 or return 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 below in Section 12.3.

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.

12.2 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, with stimulation current unchanged, until the error is cleared. Stimulation stops if the error is detected during multiple consecutive stimuli.

12.3 Electrode disconnected

When the clinician or patient attempts to start stimulation, the stimulator checks the connection of each stimulation, return and recording electrode. If one or more stimulation or return electrodes are disconnected, then stimulation will not start. If one or more recording electrodes are disconnected, then stimulation will start with closed-loop disabled and ramp from 0 mA to the stimulation current set when the stimulator stopped.

12.4 Current at maximum

If the stimulation current is at its maximum setting when closed-loop is enabled, stimulation may stop, or the patient may feel a reduction in paresthesia intensity. If recording electrodes are disconnected, then stimulation stops. If the recording electrode is reconnected, stimulation may be restarted by the patient using the EPC and will ramp to the target value set when the stimulator stopped. If the recording electrode remains disconnected the stimulator will follow the behavior described in Section 12.3.

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.

12.5 Clipping

For each stimulus, the stimulator checks the ECAP signal is within the ECAP amplifier setting limits (see Section 8.6). If clipping occurs, the stimulator may set the ECAP amplifier setting to

Low and stimulation will continue. 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 12.3.

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 12.3.

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.

13 Evoke Patient Controller

Refer to the Evoke SCS System User Manual for full details on use of the Evoke Patient Controller (EPC).

13.1 Pair EPC to stimulator

To enable the EPC to be used with an eCLS or CLS it must first be paired with that stimulator.

1. Ensure that there are no other stimulators nearby when you attempt to pair, as pairing will not occur if the EPC detects more than one stimulator.
2. With the EPC off, press and hold

and then press and hold at the same time for more than 1 second to enter pairing mode.

- While searching for the stimulator, the EPC will beep every 0.5 seconds for up to 10 seconds.

- The EPC will emit one long beep if pairing is successful.
    - The EPC will beep three times if pairing is unsuccessful because no stimulator could be detected.
    - The EPC will beep four times if pairing is unsuccessful because more than one stimulator has been detected.

3. Press to start using the EPC or to start searching again if pairing was unsuccessful.

13.1.1 Un-pair an EPC and stimulator

The EPC can only be paired to one stimulator at a time. If you need to pair to a different stimulator, you must restart pairing mode as shown in Section 13.1.

> **Note:** You do not need to un-pair the EPC from the stimulator it is already connected to before pairing with a different stimulator.

14 Evoke Charger

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

If the stimulator is being charged when connected to the CPA, an indication is displayed on the CLS icon next to the CLS battery voltage indicator. The charging indicator is updated during stimulation and impedance checks.

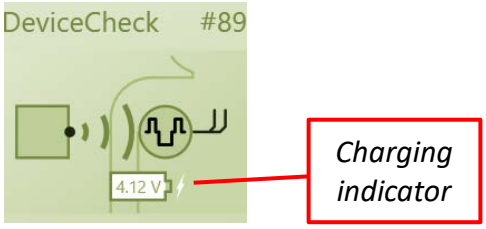


Figure 14.1: Charging indicator on the CLS icon.

14.1 Stimulation during charging

14.1.1 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.

14.1.2 Closed-loop enabled

When closed-loop is enabled:

1. Stimulation should be stopped before charging is started. Stimulation can be stopped using the CPA (see 6.14.1) 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 settings screen in Section 8.6):
   a. ☐ PCLCS Supervisor Charger Mitigation Enabled
      When 'PCLCS Supervisor Charger Mitigation Enabled' is not checked, stimulation will automatically stop when charging starts. 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. ☑ PCLCS Supervisor Charger Mitigation Enabled
      When 'PCLCS Supervisor Charger Mitigation Enabled' is checked (default), stimulation continues with closed-loop disabled when charging starts, and the stimulation current is set to the minimum from the previous 10 seconds.
5. After charging has finished, the CLS will automatically enable closed-loop stimulation. If stimulation was on during charging, the target is set to the average ECAP amplitude from the previous 5 seconds.

⚠ **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.

15 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.

16 Maintenance of the Evoke CI and Evoke CST

16.1 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.

16.2 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.

16.3 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:

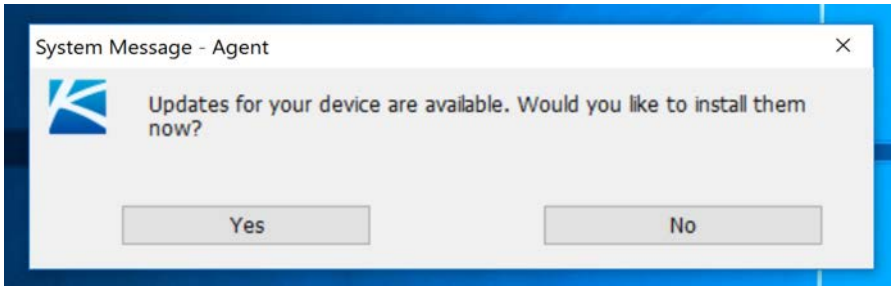


Figure 16.1: Prompt message for software update.

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.

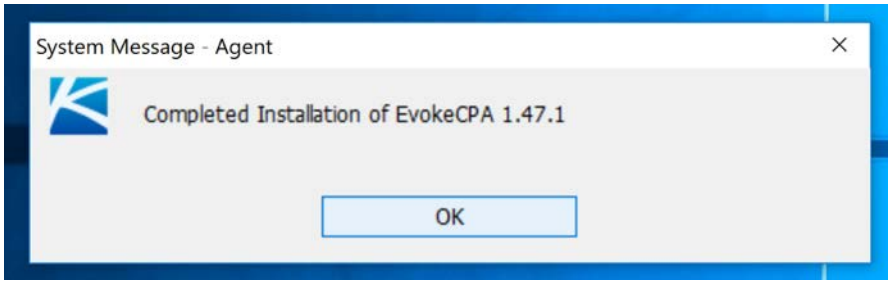


Figure 16.2: Example program update message.

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

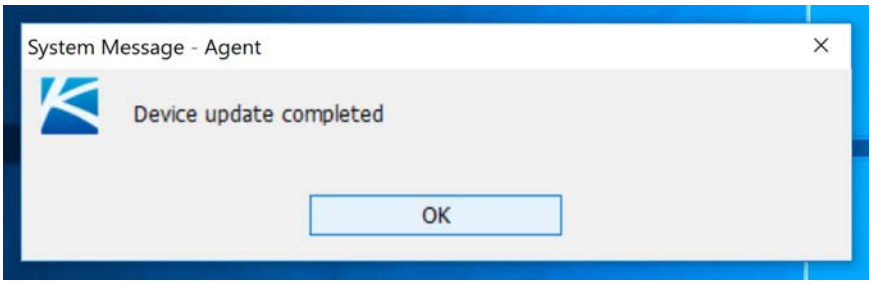


Figure 16.3: Device update completion message.

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

17 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.

18 Troubleshooting

Table 18.1: Troubleshooting.

Issue	Possible Explanation	Corrective Action
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.

Issue	Possible Explanation	Corrective Action
Programming software (Evoke CPA) icon is not visible.	Icon may have been moved or deleted.	Using the CI search function, locate and select the 'Evoke CPA'. 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 the 'Evoke CPA'. The program should start. If this procedure fails, please call your Saluda representative.
Stimulator cannot be found by CPA.	Stimulator battery may need recharging.	Charge stimulator.
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.
Red clock icon appears in main menu window.	Stimulator time is not synchronized.	Synchronize stimulator time. **Note:** Stimulation must be off.
Unable to start stimulation on CPA.	Minimum electrode configuration has not been programmed.	Configure stimulation and return electrodes (see Section 6.8).
	Stimulation parameters may be too high.	Check pulse width, frequency, maximum current and interphase gap (IPG) and ensure the combination in use is within system limits.
Cannot enable Closed-Loop on CPA.	Recording electrodes have not been configured.	Configure recording electrodes (see Section 6.10).
	Sampling period may be too small.	Increase sampling period/number of samples ('+' button).
Parameter or control button greyed-out.	Parameter may be at maximum allowable for current program.	Assess the level of all stimulation parameters.
	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 (green background).	System may be busy.	Wait for condition to clear or re-start software. Close other applications that are running.
	Communication may be disrupted.	Move CST closer to device. Ensure no EMI from other devices.
Rolling plot lacks data points and appears 'lumpy'.	System may be busy.	Wait for condition to clear or re-start software. Close other applications that are running.

Issue	Possible Explanation	Corrective Action
	Communication may be disrupted.	Move CST closer to device. Ensure no EMI from other devices.
Software freezes or has very slow response.	Other applications open.	Re-start software. Close other applications that are running.
Patient cannot raise stimulation to their desired level using the EPC.	Maximum stimulation current may be too low.	Raise Maximum Stimulation Current (see Section 8.1).
	ECAP Target Maximum may be too low.	Raise ECAP Target Maximum (see Section 8.2).
Patient or Programming clinician cannot raise stimulation above zero with the EPC.	Stimulator may be in Safe Mode.	Perform 'Soft Reset and Reconnect'.
	Stimulator may be reaching voltage compliance limit (See 'Out of Compliance'). Stimulator may have Electrode Disconnected error (See 'Electrode Disconnected').	See 'Out of Compliance'. See 'Electrode Disconnected'. **If an eCLS** Check intraoperative cable, lead adapter and eCLS connections. Perform an impedance check to ensure all connections are ok. **If a CLS** Perform an impedance check to ensure all connections are ok.
	EPC may not be communicating with the stimulator.	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 (refer to Section 6).
	Patient is moving while charging the CLS or eCLS	The CLS will only operate with CL disabled while the it is being charged. Stimulation should be turned off or the patient should not move too much if the stimulation strength variation is unpleasant.
Contact Clinician Indicator Light is on either Charger or EPC.	Stimulator is in Safe Mode.	Note down the error on the screen. Perform 'Soft Reset and Reconnect'.
Interface connection error.	CST is not plugged in.	Plug CST into USB port.

Issue	Possible Explanation	Corrective Action
Clipping causes stimulation to stop.	Recording Electrode is disconnected.	Check electrode connectivity with an impedance check.
	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.
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 maximum current limit.
	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.
	Electrode disconnection.	Check the impedances. See 'Electrode Disconnected'.
	CL stimulation is on when charging is started.	Turn off the Charger and see if the problem persists.
Out of Compliance.	Voltage limit may be too low.	Confirm voltage limit is set to 15 V (maximum).
	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. 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.	Repeat download of log file.
Electrode disconnected.	Electrode may be broken, or in highly resistive tissue.	Reprogram using a different electrode.
	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.

19 Package contents

Table 19.1: 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)

20 Technical Specifications

20.1 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.

20.1.1 Evoke CI Tablet specifications

The CI tablet computer has minimum hardware specifications as follows:

Table 20.1: 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

20.1.2 Evoke CST specifications

Table 20.2: 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)		
Communications Link	USB connection between laptop and CST. USB port current limit 500 mA MICS band (402–405 MHz) half-duplex radio frequency communication. CST – Master, to 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 (FSK)	
	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		
Storage & Transportation Conditions	Temperature:	Min: -20 °C (-4 °F)	Max: 60 °C (140 °F)
	Humidity:	Min: 0% RH	Max: 90% RH
Operating Conditions	Temperature:	Min: 5 °C (41 °F)	Max: 40 °C (104 °F)
	Humidity:	Min: 15% RH	Max: 90% RH
	Pressure:	70 kPa (0.69 atm)	Max: 106 kPa (1.05 atm)

20.2 Wireless Communication

20.2.1 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 20.3).
- 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.

20.2.2 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.

20.3 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.

20.3.1 Guidance and Manufacturer's Declarations

Table 20.3: Electromagnetic emissions.

<table>
<tr><td colspan="3">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.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Radiated disturbance, 30 MHz - 6000 MHz CISPR 11 (EN 55011)</td><td>Group 1, Class B</td><td>Evoke SCS System is unlikely to produce electromagnetic interference with nearby electronic equipment.</td></tr>
<tr><td>Conducted Emissions 0.15 MHz -30 MHz CISPR 11 (EN 55011)</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Not applicable for the battery powered devices or device consuming less than 75 W from mains power outlet
(Charger with power adapter)</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Not applicable for the battery powered devices. Charger with power adapter complies with requirements of the standard</td></tr>
</table>

Table 20.4: 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 20.5: 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.	

20.4 Federal Communications Commission (FCC)

20.4.1 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.

20.4.2 Charger

This device complies with Part 18 of the FCC Rules.

20.4.3 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.

21 Glossary

Table 21.1: 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.

Term	Definition
	Maximum (M) The activation level the patient could tolerate for no more than approximately one minute.
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.
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.
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 (Virtual Ground)	A feature of the stimulation pulse that is used to reduce the artefact recorded during measurement by cancelling the artefact from the stimulation and return electrodes. ClearCAP is labeled as 'Virtual Ground' in the CPA.
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.
Clinical Data Viewer (CDV)	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.

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.
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.
Intraoperative Cable	Sterilized cable which enables the connection between leads/lead extensions and the eCLS.

Term	Definition
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 a 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 CDV.
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.
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.
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.

Term	Definition
Program	The complete set of parameters describing stimulation, recording, measurement and feedback. A program may contain up to 4 Stimulation Sets.
Rheobase	The minimum stimulus current needed for neural activation at an infinitely long pulse width.
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.
Stimulation	The application of electrical current through electrodes.
Stimulation Set	A set of stimulation parameters designed to target a particular area of the patient's pain.
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.

22 Symbols

Table 22.1: Symbols.

Symbol	Definition
www.saludamedical .com/manuals	Follow the instructions for use at this website: www.saludamedical.com/manuals
	Follow the instructions for use
	Caution
REF	Catalogue number
SN	Serial number
LOT	Lot number
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
	Do not use if package is damaged
MR	MR Unsafe. Not safe to use with MR imaging
Qty	Contents
	Class II Medical Electrical Equipment

Symbol	Definition
	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.
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

23 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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