Evoke™ SCS System Clinical Manual

Use of the Evoke™ System including recommendations for programming the Evoke™ Closed Loop Stimulator (CLS) and the Evoke™ External Closed Loop Stimulator (eCLS)

CAUTION – Investigational Device.
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1 Description

The Evoke™ System is a Spinal Cord Stimulation (SCS) system that can measure the Evoked Compound Action Potential (ECAP) and may provide consistent stimulation based on the subject's neural response during physiological changes and movement by automatically adjusting the level of stimulation current required to meet the subject's requested target level.

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

The Evoke™ System comprises several key components to deliver the therapy.

Table 1.1: Description of Evoke™ System components

Name: Evoke™ Closed Loop Stimulator (CLS) **Ref Number:** 0002 The Evoke™ Closed Loop Stimulator (CLS) is a totally implanted spinal cord stimulator that connects to the leads and is implanted under the skin for long-term therapy. The CLS delivers stimulation through the leads and measures the neural response to stimulation.
Name: Evoke™ External Closed Loop Stimulator (eCLS) **Ref Number:** 0020 During the trial stimulation period, the leads are connected to the Evoke™ External Closed Loop Stimulator (eCLS). The eCLS is an external stimulator worn during the trial stimulation period. The eCLS delivers stimulation through the leads and measures the neural response to stimulation.
Name: Evoke™ 12C Percutaneous Leads **Ref Number:** 0008, 0026 (permanent lead length 60 cm) 0016 (trial lead length 60 cm) 0009, 0027 (permanent lead length 90 cm) 0017 (trial lead length 90 cm) 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 with 12 electrodes on each lead are implanted.
Name: Evoke™ Lead Adapter Kit **Ref Number:** 0028 The Evoke™ Lead Adapter, Lead Adapter Cable and Lead Adapter Extension allow you to connect the eCLS to the implanted leads.

Name: Evoke™ Pocket Console (EPC) **Ref Number:** 0003 The Evoke™ Pocket Console (EPC) allows the patient to control their therapy and actively monitors Stimulator battery status and other elements of the system. The EPC and the Stimulator communicate with each other wirelessly.
Name: Evoke™ Charger **Ref Number:** 0006 The Evoke™ Charger allows you to recharge the battery in a CLS. The charging coil (attached to the Charger) is placed over the CLS and the charge is transferred through the skin from the Charger to the CLS. The Charger kit also includes a power adapter for recharging the Charger.
Name: Evoke™ Clinical Interface (CI) **Ref Number:** 0024 The Evoke™ Clinical Interface (CI) is a tablet computer with a programming application used by the clinician to adjust the therapy settings in the Evoke™ CLS or Evoke™ eCLS.
Name: Clinical System Transceiver (CST) **Ref Number:** 0004 The Clinical System Transceiver (CST) is a plug in device (USB connection) that enables exchange of information wirelessly between the CI and the stimulator.

2 Intended 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™ System should not be used in patients who:

- Do not receive effective pain relief during trial stimulation.
- Are unable to operate their system.
- Are unsuitable surgical candidates.

4 Safety Information

Patients must be advised of the following warnings and precautions.

4.1 Warnings

Diathermy

- Patients implanted with the Evoke™ System should not be subjected to shortwave, microwave and/or therapeutic ultrasound diathermy.
- Diathermy generates energy that may cause heating at the percutaneous lead site resulting in damage to the CLS, tissue damage, severe injury or death.

Magnetic Resonance Imaging (MRI)

- As the Evoke™ System has not been tested for MRI compatibility, it is considered MRI unsafe.
- Patients implanted with the Evoke™ System should not be subjected to MRI as it may result in significant heating and/or tissue damage.
- MRI exposure can damage the CLS, potentially requiring device explantation and replacement.
- MRI exposure may also induce voltages through the leads and stimulator leading to unintended stimulation, such as tingling, shocking, or jolting.

CT Scans

- Patients implanted with the Evoke™ System may experience a momentary increase in stimulation when receiving a CT scan. Some patients have described this as uncomfortable stimulation, jolting or a shocking sensation.
- Prior to a patient undergoing a CT scan, turn the CLS off.

Electrosurgery

- Patients implanted with the Evoke™ System should not be subjected to electrosurgical techniques, such as electrocautery, in close proximity to the Evoke™ system components.
    - Electrosurgical devices generate energy that may cause tissue damage at the lead site and result in severe injury.
    - Damage may also occur to the CLS.

Interference with implanted cardiac devices

- The Evoke™ System may interfere with other implanted stimulators with sensing capabilities such as demand type pacemakers or cardioverter defibrillators.
- The effects of implanted stimulation devices on the Evoke™ System is unknown.

Stimulator damage

- If the CLS case is ruptured or pierced, then patient tissue may be exposed to battery chemicals, which could lead to burns or tissue damage.
    - Do not implant the CLS if the case is damaged.

Electromagnetic interference

- Strong electromagnetic fields may turn the stimulator off, cause uncomfortable or jolting stimulation or affect communication with the EPC.
- Patients should be advised to avoid or turn stimulation off around:
    - Security screeners such as those used at of department stores, public buildings, and airports – patients should present their implantable device ID card and request to go around the screener; but if they are required to go through the screener they should turn stimulation off.
    - Power lines or power generators.
    - Electric steel furnaces and arc welders.

- Large, magnetized stereo speakers.
- Tag deactivators such as those found in retail stores and libraries.

Heat due to charging

- During charging, the Charger and/or CLS may become warm.
- Patients should not charge while sleeping or with the charging coil in contact with their skin for prolonged periods as this may result in heating that can cause redness, skin irritation or a burn.
- If patients experience pain or discomfort, they should cease charging and contact Saluda Medical.

Notification of an implanted stimulator prior to any other surgical procedures

- Some surgical procedures that use electrical current could affect the patient's implanted stimulator and leads, cause serious injury, and may damage the stimulator
- Patients should be advised to inform their clinician prior to any procedure that they have an implanted stimulator so the procedure can be conducted without using electric current near the implanted stimulator or leads.

Uncomfortable changes to the stimulation strength due to movement

- Any changes in posture may cause an uncomfortable change or a painful increase in the stimulation strength patients feel.
- Patients should turn down the stimulation strength or turn off the stimulation before making posture changes.

The Evoke™ System has not been tested for use in patients who are pregnant or nursing.

The Evoke™ System has not been tested for use in patients under 18 years old.

4.2 Precautions

Physician training

- Implanting physicians should be trained in spinal cord stimulation (SCS) procedures.
- Physicians should review the surgical guide before surgery.

Medical imaging

- MEG, PET, x-ray/fluoroscopy and diagnostic ultrasound are unlikely to affect the Evoke™ System.

Medical therapies

When used in close proximity to the Evoke™ System, the following medical therapies may turn stimulation off or cause damage to the CLS:

- Lithotripsy
- Electrocautery
- External defibrillation
- Radiation therapy (any damage to the device by radiation may not be immediately detectable).
- Ultrasonic scanning
- High-output ultrasound

- TENS
- Psychotherapeutic procedures (e.g. electroconvulsive therapy, transcranial magnetic stimulation).
- Laser procedures

If the patient is required to undergo these therapies:

1. Turn off stimulation.
2. Disconnect the eCLS if one is in use
3. Ensure all fields, electrodes, probes and/or ground plates are as far away as possible from the Evoke™ System.
4. Use the lowest energy setting needed for the therapy.
5. Check the functioning of the Evoke™ System after the procedure and contact Saluda Medical if any problems are apparent.
6. For electrocautery, use bipolar mode if available.

Operating equipment

- Patients may be distracted from operation of equipment if there are sudden stimulation changes.
- Patients should turn stimulation off before operating automobiles, other vehicles, or potentially dangerous equipment.

Post-operative patient instructions

After implant of the Evoke™ System, patients should take care to allow adequate healing and ensure that the leads and CLS do not move.

- For six to eight weeks after surgery, patients should avoid:
    - lifting more than 2.2 kg (5 lbs);
    - physical activities requiring stretching, bending or twisting;
    - raising their arms above their head.
- Patients may experience temporary pain at the implant site as the incisions heal after the surgery.
- Patients may experience redness or irritation at the implant site, in which case they should contact their physician to check the wound for infection or adverse reaction to the implanted materials.

Stimulator manipulation

- Patients should avoid manipulating the Evoke™ System through the skin as it may cause damage, lead or CLS movement, pain, irritation, or skin erosion.
- If the CLS is “flipped” over inside the skin pocket it may no longer be able to be charged.

Scuba diving

- Patients should always obtain advice from their clinician prior to any diving activities.
- Patients should not dive below 5 m (16 ft.) or use hyperbaric chambers above 150 kPa (1.5 atm).
- The CLS may be damaged at greater depths or pressures.

Implant failure

- It is possible for the stimulator to stop working due to failure of a component or battery, or a broken wire.

- Patients should be advised to charge their stimulator fully and, if it still fails to work, contact the Clinician.

Sterilization and storage

- All surgical and implantable components of the Evoke™ System are supplied sterile.
- The sterilized components of the Evoke™ System are sterilized using ethylene oxide.
- All Evoke™ sterilized components are single use only and should not be re-sterilized or reused, because of the risk of infection and device malfunction.
- Please observe the storage conditions printed on the labels of each component – particularly storage and transport temperature, which varies between components – as inadequate storage could have a negative impact on shelf-life and sterility.
- Please observe the expiration dates printed on the labels and return any expired product to Saluda Medical because of the risk of infection.
- If the packaging appears to be damaged, please return it to Saluda Medical for replacement.
- Patients should be advised to avoid storing the Evoke™ external accessories outside the labeled temperature ranges or in steamy environments such as bathrooms and to keep them dry.

Handling of the eCLS, EPC and Charger

- Patients should be advised to carry and hold their accessories carefully to protect them from striking hard surfaces or being dropped.
- Patients should be advised to keep their accessories dry and never immerse them in water.
- Patients should be advised to not plug the Charger into outlets that are in humid environments – such as a bathroom – or near water.
- If patients need to clean their accessories, refer them to the Evoke™ Instructions for Use.
- Avoid prolonged skin contact of the external system components (lead adapter, lead adapter cable, lead adapter extension, eCLS, EPC and Charger and charging coil). Place clothing or dressings between skin and external system components.

Disposal of the stimulator, EPC and Charger

- The CLS, eCLS, EPC and Charger contain batteries that could explode if they are thrown into a fire.
- The CLS, eCLS, EPC and Charger should be returned to Saluda Medical.

Disposal of sharps and explanted implants

- Please dispose of any sharps and medical waste according to your usual procedures.
- If you have explanted any component of an Evoke™ System for any reason please contact Saluda Medical to arrange for its return.

Modifications to components

- The components of the Evoke™ System are not intended to be modified by users or surgeons in any way.

4.2.1 Unsupported software applications

⚠Do not load 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.

4.2.2 Unsupported hardware

⚠Do not connect any device to the Evoke™ CI other than the supplied**:** keyboard, Charger 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 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.

4.2.3 Shared IT networks

Network connection is only permitted to secure networks. Connecting to unsecure networks could lead to the modification of CI System or software that interfere in unpredictable ways with the programming software installed and affect the delivery of therapy for patients.

4.2.4 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.

4.2.5 Non-sterile components

DO NOT STERILIZE either the CI or CST; these items are not to be sterilized and doing so could irrevocably damage the devices.

4.2.6 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.

4.2.7 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.

4.2.8 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 whilst 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.

4.3 Potential Risks

Every surgery involves potential risks, including death. In addition to these surgical risks, the risks associated with the implantation and use of a spinal cord stimulation system include:

- Undesirable changes in stimulation sensation and/or location.
- Uncomfortable changes in stimulation (over and/or under stimulation).
- Persistent post-surgical pain at hardware implantation sites.
- CLS migration, which may result in pain or difficulty in charging.
- Seroma or hematoma at surgery sites.
- Epidural hemorrhage, spinal cord injury and possible paralysis.
- Lead migration from the location chosen at initial implantation resulting in stimulation changes.
- Breakage of the lead or failure of other system components, which may result in loss of stimulation.
- Rejection of, or allergic reaction to, the implanted components.
- Infection that may require hospitalization with intravenous antibiotic therapy.
- Cerebrospinal fluid (CSF) leakage.
- Inadequate pain relief following system implantation.
- Erosion of the lead, or CLS through the skin.

- Weakness, clumsiness, numbness or pain below the level of lead implantation.

Note: The patient may require surgery (including revision, explant and replacement) as a result of any of the above.

5 Intra-Operative Programming with the CI

Note: The Evoke™ Surgical Guide provides specific information about surgical procedures and necessary connections between leads/extensions/lead adapter/CLS/eCLS as required for the various procedures.

Note: Neither the CI nor the CST are supplied sterile and should not be used inside the sterile field during intra-operative programming; see Evoke™ Surgical Guide for details.

5.1 Confirmation of 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 or through paresthesia mapping using intraoperative patient feedback.

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

5.1.1 Connect the lead adapter extension to the eCLS

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

1. Connect the lead adapter cable (or lead adapter extension) to the eCLS (refer to Figure 5.1).

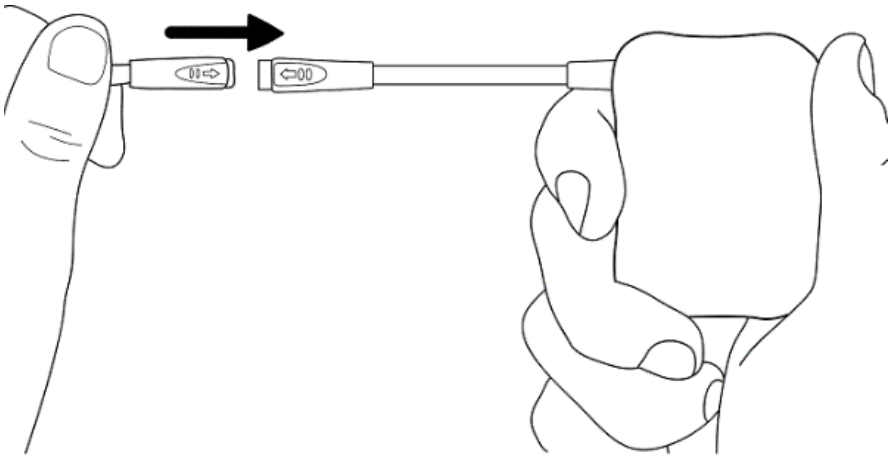


Figure 5.1: Connect the lead adapter cable (or lead adapter extension) to the eCLS.

5.1.2 Confirmation of optimal lead placement

- If confirmation of optimal lead placement will be based on ECAP measurement, go to section 5.1.2.1.
- If paresthesia mapping is to be performed, go to section 5.1.2.2.

5.1.2.1 ECAP measurement

This section is to be completed by the programming clinician outside of the sterile field. Refer to section 7 'Clinical programming ' for detailed programming instructions.

1. Connect the CI to the eCLS.
2. Check electrode impedance using the CI to ensure the leads are connected properly.
    - If electrode impedance is greater than 4000Ω check all the connections.
    - Check impedance after each reconnection of the proximal connector to the lead adapter
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 CI or move the percutaneous lead to a new position.
    - Verify ECAP measurement after changing settings or moving the percutaneous lead.
5. When satisfied with the lead placement, turn stimulation off and disconnect the eCLS from the lead adapter extension.
6. The surgeon then disconnects the lead adapter from the lead.

5.1.2.2 Paresthesia mapping

This section is to be completed by the programming clinician outside of the sterile field. Refer to section 7 'Clinical programming ' for detailed programming instructions.

1. Connect the CI to the eCLS.
2. Check electrode impedance using the CI to ensure the leads are connected properly
    a. If electrode impedance is greater than 4000Ω check all the connections.
    b. Check impedance after each reconnection of the proximal connector to the adapter.
3. Select the stimulation and measurement electrodes and settings.
4. Increase stimulation current until the patient reports a medium level of paresthesia (tingling).
5. Adjust settings to ensure that ECAPs are being measured correctly.
    a. The patient should report paresthesia coverage of the body that aligns with their pain area.
    b. If paresthesia coverage is not satisfactory, change the electrode and stimulation settings using the CI or move the percutaneous lead to a new position.
6. Retest paresthesia coverage after changing settings or moving the percutaneous lead.
7. When satisfied with the lead placement, turn stimulation off and disconnect the eCLS from the lead adapter extension.
8. The surgeon then disconnects the lead adapter from the lead.

5.2 Confirmation of Proper 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. 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 radio link (see section 8.1).
2. Check electrode impedance using the CI to ensure the proximal connectors are connected properly (see section 8.1).
    - If electrode impedance is greater than 4000Ω check all the connections.
    - Check impedance after each reconnection of the proximal connector to the CLS header block.
3. The surgeon tightens the set-screw on the CLS header when satisfied that there is a proper connection.
    - Always check the impedance before tightening CLS header set-screw.

6 Post-Operative Procedures

The Stimulator can be programmed when the patient has recovered sufficiently to interact with the programming clinician.

1. Train the patient on use of the EPC, eCLS and guidelines for recovery after implant surgery (see Evoke™ User Manual).
2. If the patient has a CLS, also train them on correct use of the Evoke™ System Charger (see Evoke™ User Manual).
3. If the patient has externalized leads for a temporary trial using an eCLS, go to section 6.1. (Connecting an eCLS to Externalized Leads).
4. If the patient has an implanted CLS, go to section 7 ‘Clinical programming ’.

6.1 Connecting an eCLS to Externalized Leads

6.1.1 Connect the lead 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 6.1).

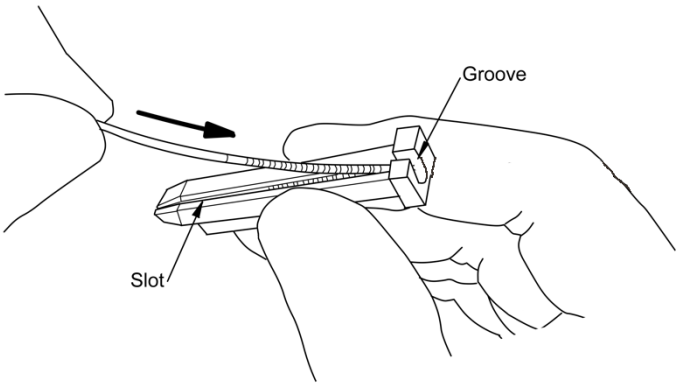


Figure 6.1: Placing the proximal connector into the lead adapter slot.

2. Push the lead down into slot completely using finger (Figure 6.2), 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.

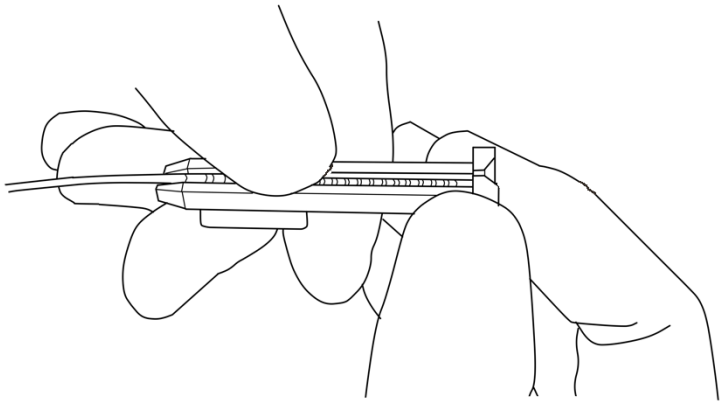


Figure 6.2: Pushing lead into slot.

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 6.3).

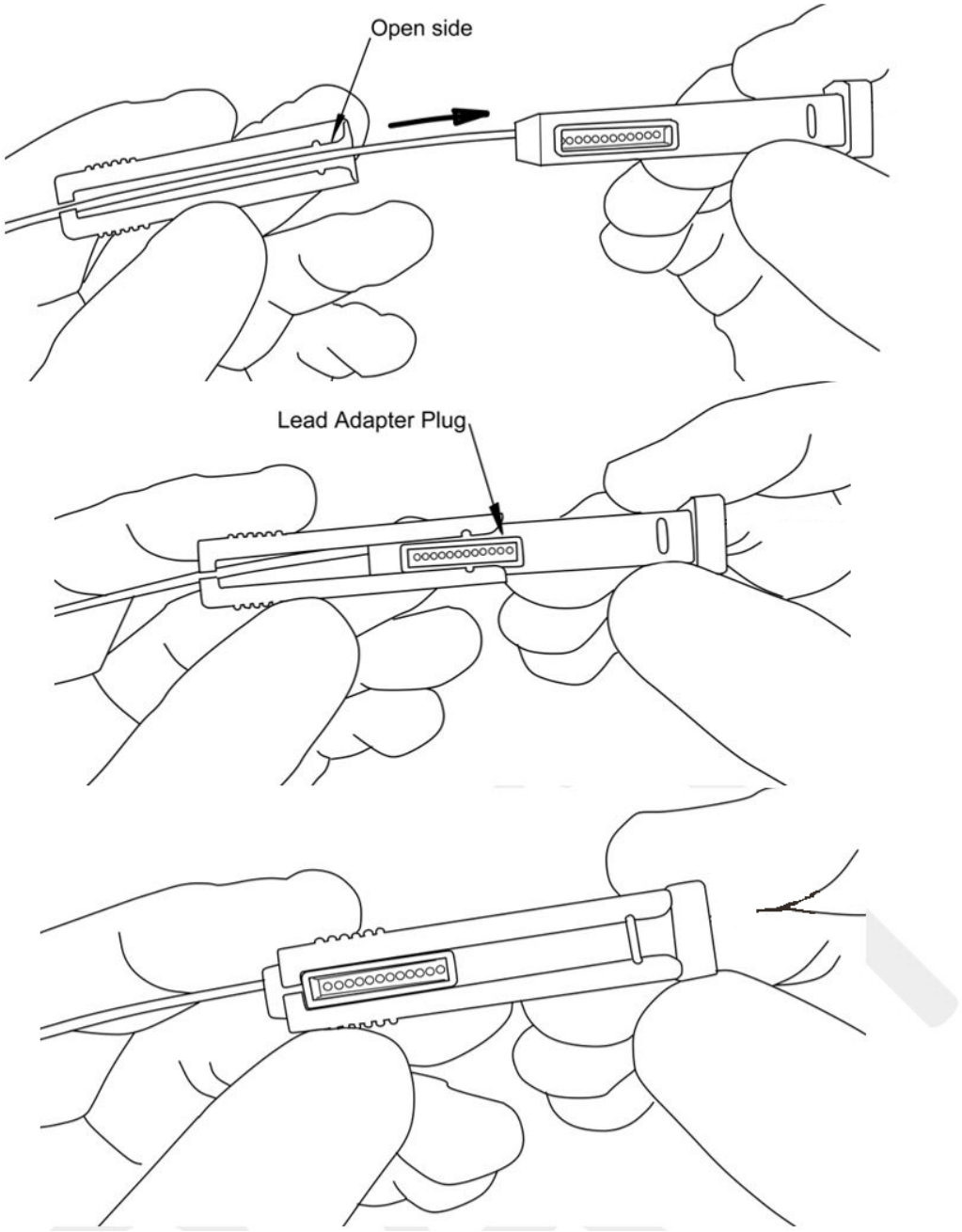


Figure 6.3: Placing the top cover over the lead and sliding onto lead adapter until it clips into place

4. Line up the end of lead adapter plug with the end of the socket in the lead adapter cable at an angle to ensure the connector pins do not get bent (Figure 6.4). Push the lead adapter plug into the socket on the lead adapter cable until it clips into place.
    a. The lead adapter cable is labelled “1” on one side for electrodes 1-12 and “2” on the other side for electrodes 13-24.

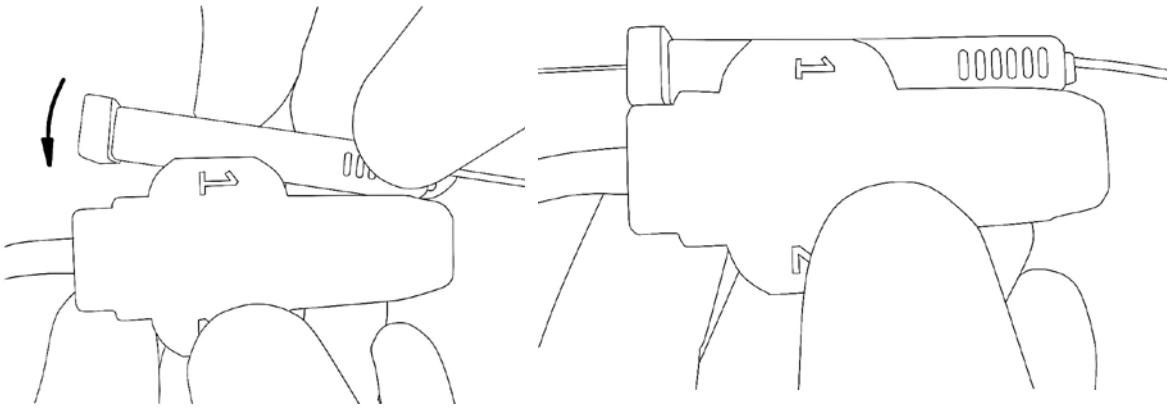


Figure 6.4: Placing the lead adapter plug into the socket on the lead adapter cable.

5. To connect a second lead to the lead adapter repeat the above steps 1 to 4 (see Figure 6.5).

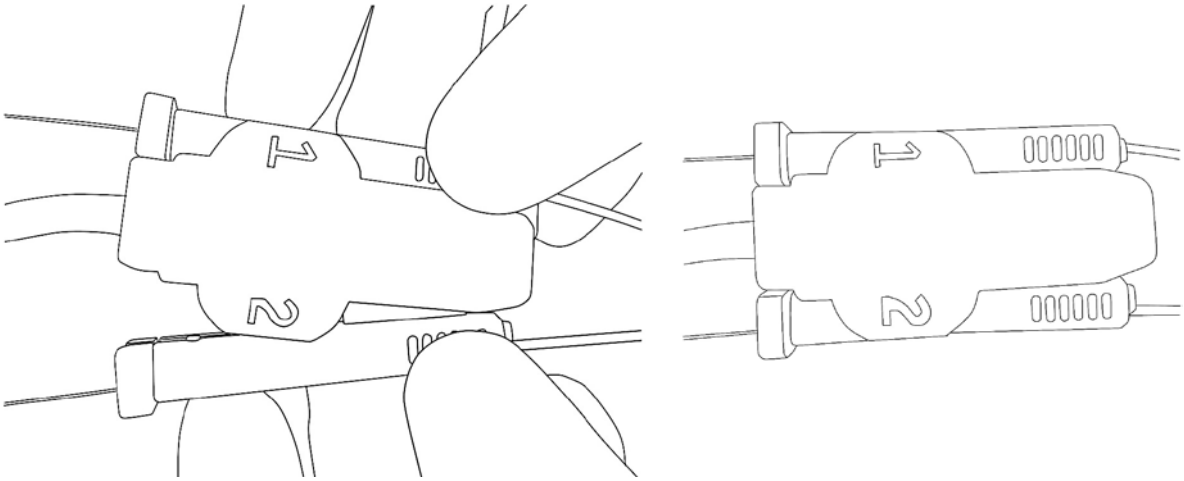


Figure 6.5: Placing a second lead adapter into the lead adapter cable.

6.1.2 Connect the lead adapter cable to the lead adapter extension

Plug the lead adapter extension into the distal connector of the lead adapter cable until you feel a gentle click.

Note: use of a lead adapter extension is optional.

6.1.3 Connect the lead adapter cable or lead adapter extension to the eCLS

Plug the lead adapter cable or lead adapter extension into the port on the eCLS until you feel a gentle click (refer to Figure 6.4).

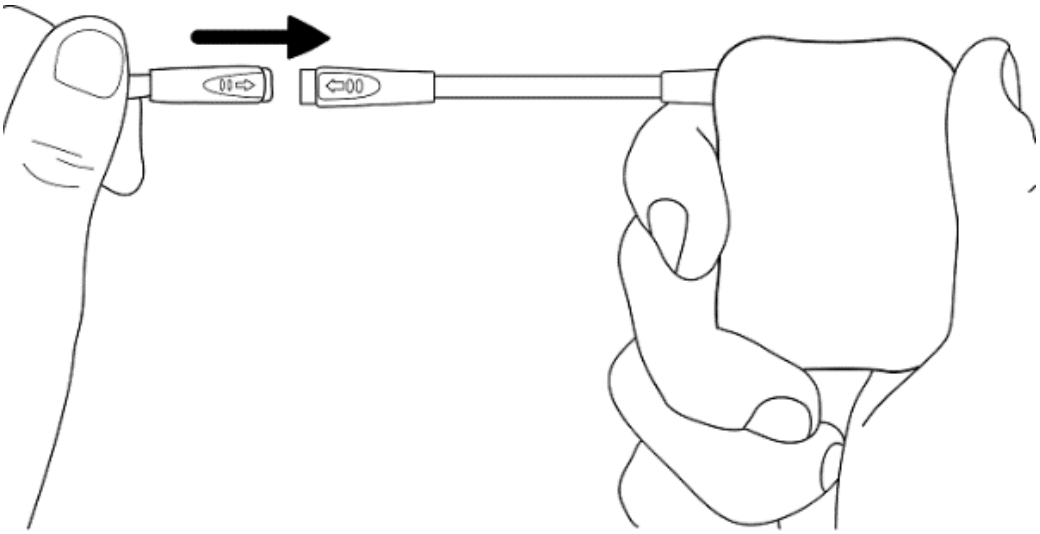


Figure 6.6: Connect the lead adapter cable or lead adapter extension to the eCLS.

⚠ **Caution:** Avoid prolonged skin contact of the lead adapter, lead adapter cable, lead adapter extension and eCLS. Place clothing or dressings between skin and external system comonents.

7 Clinical programming - Introduction

7.1 Clinical Interface (CI)

The CI is a Microsoft Surface Pro 4 tablet computer. Figure 7.1: Basic Physical Properties of CI. shows basic physical configuration. Full specifications for the tablet computer hardware are available at https://www.microsoft.com/surface/en-au/support/browse/surface-pro-4. 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.

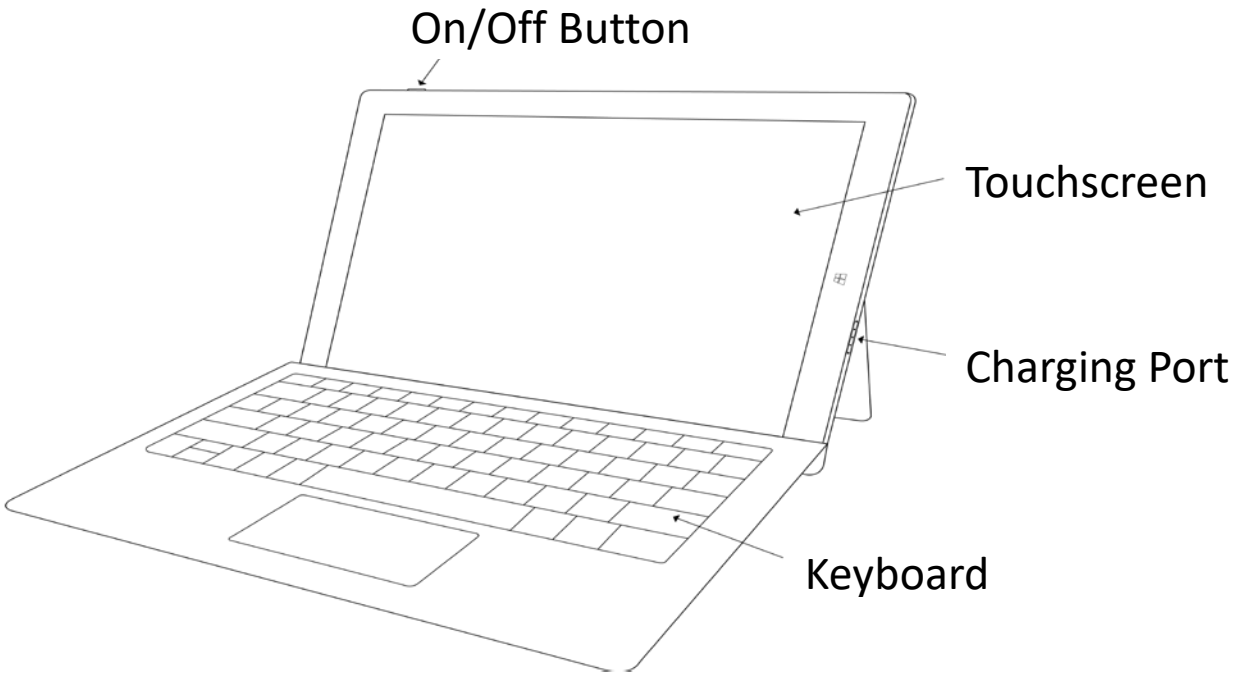


Figure 7.1: Basic Physical Properties of CI.

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. Should the CI operator or the CI operator's organisation wish to change this password it is their responsibility that all potential operators are aware of this password and can easily access it should it be forgotten.

7.2 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.

8 Clinical Programming – Using the CPA

8.1 Programming overview

1. Test stimulation from several electrodes (see section 8.7 and 8.8) and ask the patient to report where they feel paresthesia.
2. Determine the stimulation electrodes that give the best paresthesia coverage of the patient's pain.
3. Determine the settings that provide a good measurement of the neural response to stimulation (ECAP – see section 8.9).
4. Determine the settings for optimum Evoke™ Feedback Control (FC) therapy (see

section 8.10).

5. Save the program to the CLS memory (see section 8.12) and proceed to set up a maximum of four programs.

8.2 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. Connect the CST to the CI with the USB connection (see Figure 8.1).

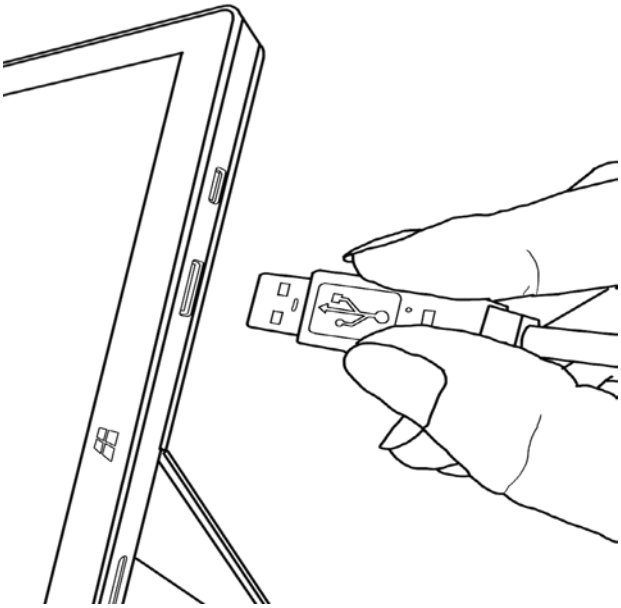


Figure 8.1: Connecting the CST to the CI

2. Position the CST near the stimulator and double-click the Evoke™ Clinical Programming Application (CPA) icon to start the program (see Figure 8.3 for the main screen layout).

   Note: The CST can link with the stimulator within a 1.0 m (3.3 ft) radius.
   Note: EMI can affect the quality of this wireless link, see section 4 – Warnings and precautions.

3. Chose the appropriate Visit Name from the dropdown menu (see Figure 8.2).

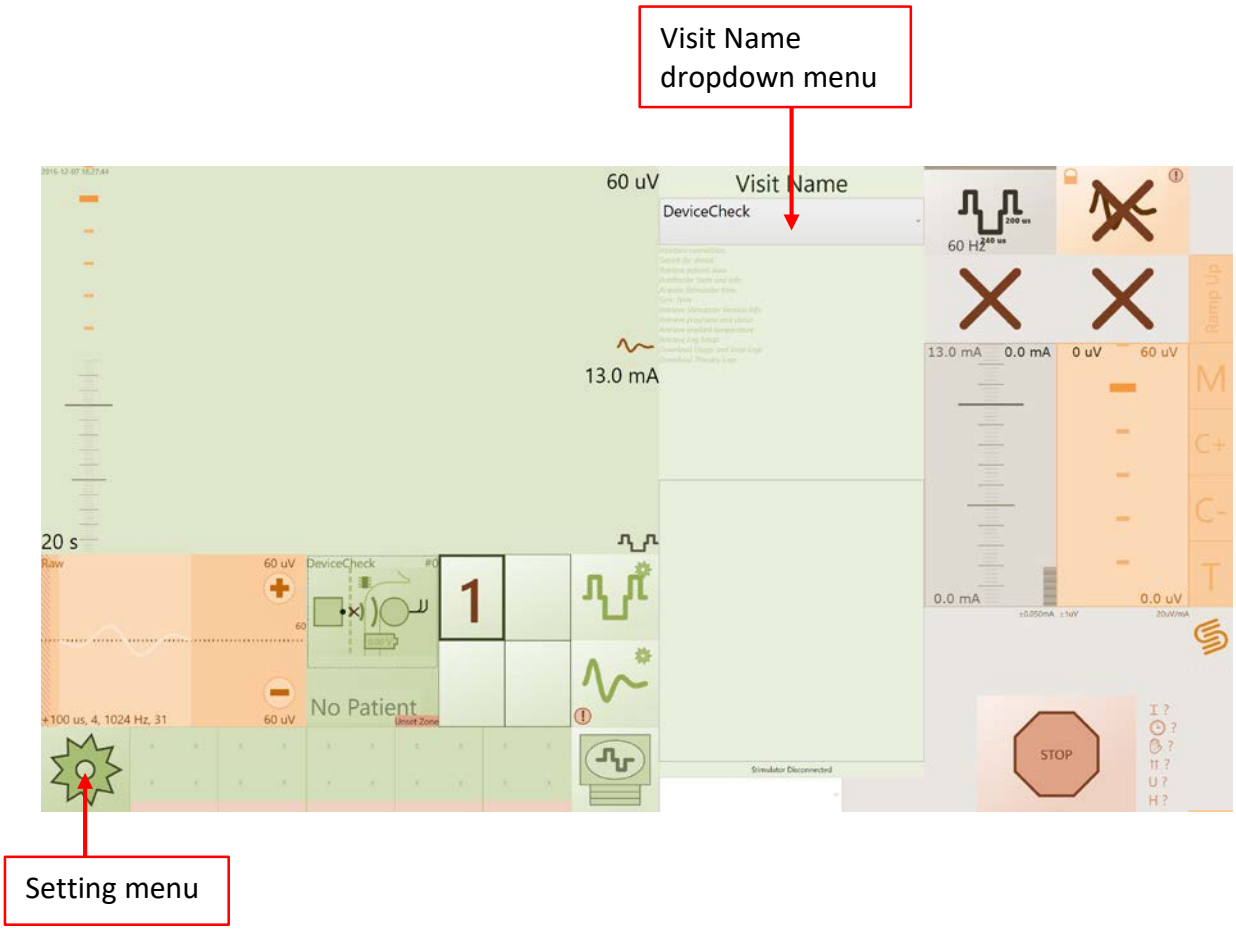


Figure 8.2: Location of the Visit Name dropdown menu and setting button

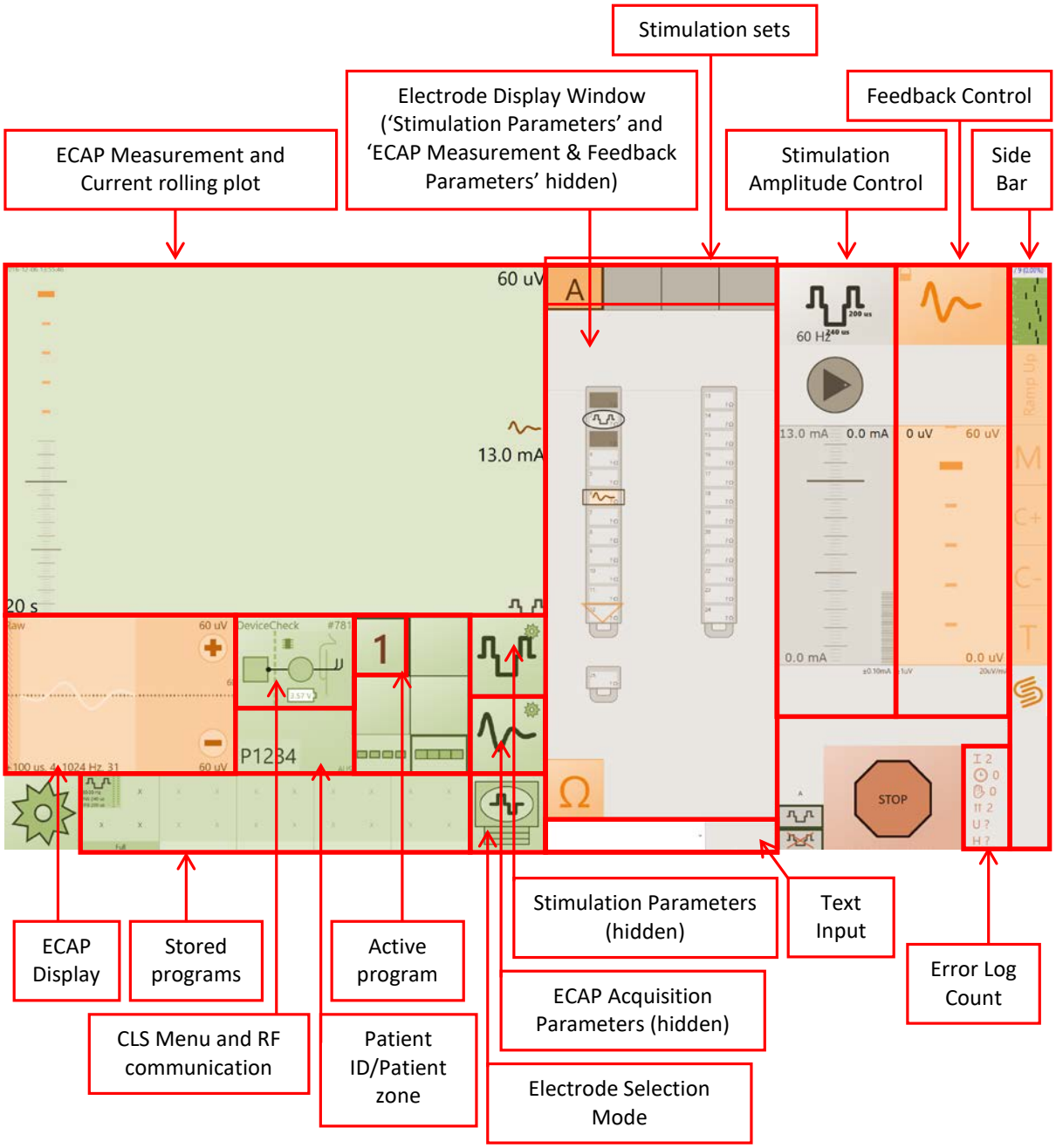
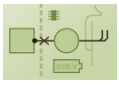


Figure 8.3: Functional layout of the CPA main screen.

4. Touch the *CLS Icon*  to open the CLS Menu (see Figure 8.3 for icon location).
5. Touch *Connect to Implant* in the CLS Menu to search for nearby stimulators.
6. Click on the stimulator serial number that you wish to connect to.

   Note: If there is only one stimulator nearby the application will select that stimulator automatically. You may check the serial number in the CLS menu.

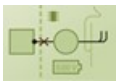
7. The CPA will connect to the stimulator and retrieve any patient data and programs.

   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.

8. 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 Measurement and Current rolling plot (see section 9.8). To download the logs manually, such as when download fails, refer to section 9.6.

8.3 Set stimulator time

1. Touch the CLS icon  to open the CLS Menu.
2. Touch *Synchronize Stimulator 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.

8.4 Retrieve or set the Patient ID and Patient Zone

8.4.1 For an existing patient

1. On connection to the stimulator the Patient ID is retrieved and displayed under the CLS icon (see Figure 8.4).

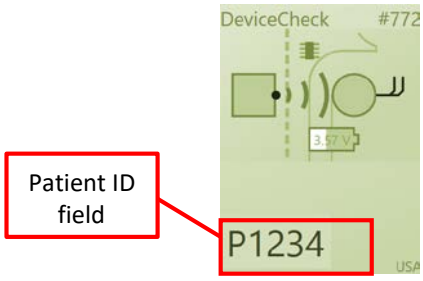


Figure 8.4: CLS Icon with Patient ID underneath.

2. Check that the correct ID has been retrieved.

8.4.2 For a new patient

1. For a new patient, touch the *Patient ID* box under the CLS icon (see Figure 8.4).
2. Delete any existing text and enter the new Patient ID.
3. Touch the *Done* button that appears above the ID when you finish typing (see Figure 8.5).
4. Navigate to the settings page by tapping the Setting Menu and select the appropriate Patient Zone (see Figure 8.6).

Figure 8.5: CLS Icon with Patient ID and Done button.

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

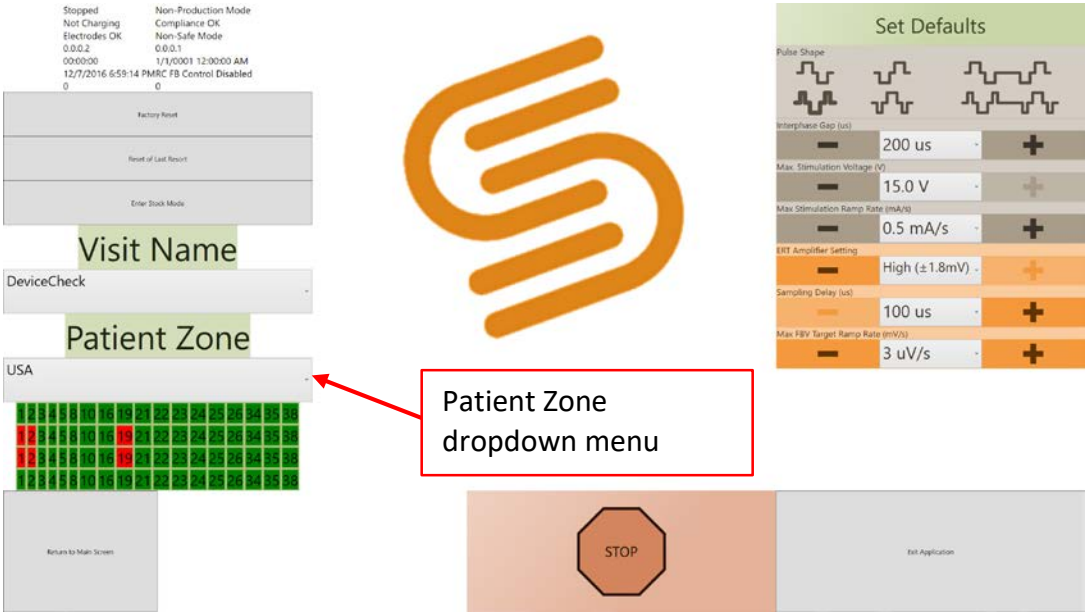


Figure 8.6: Settings Menu with Patient Zone dropdown menu highlighted

8.5 Measure electrode impedance

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

1. Touch the *Impedance* icon Ω

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

2. The impedance on the 24 electrodes and CLS case will be shown on the electrode selection panel (see Figure 8.7).

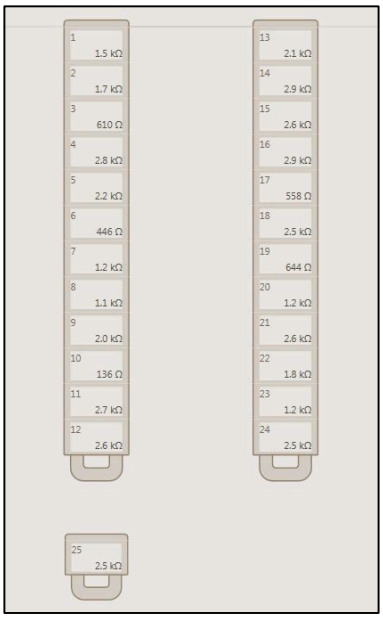


Figure 8.7: Impedances displayed on the 24 electrodes and CLS case.

- Electrodes with a cross through them  are disconnected (> 4000 Ω) and cannot be used for stimulation or recording.
- 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 (disconnected):

- Wipe any blood or fluid off the lead connection contacts.
- If the system is fully implanted, high impedance may indicate that the lead is broken or dislodged from the header and the patient may require revision surgery if stimulation is insufficient.

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

8.6 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 8.8). This will aid in determining the best stimulation and measurement electrode combination.

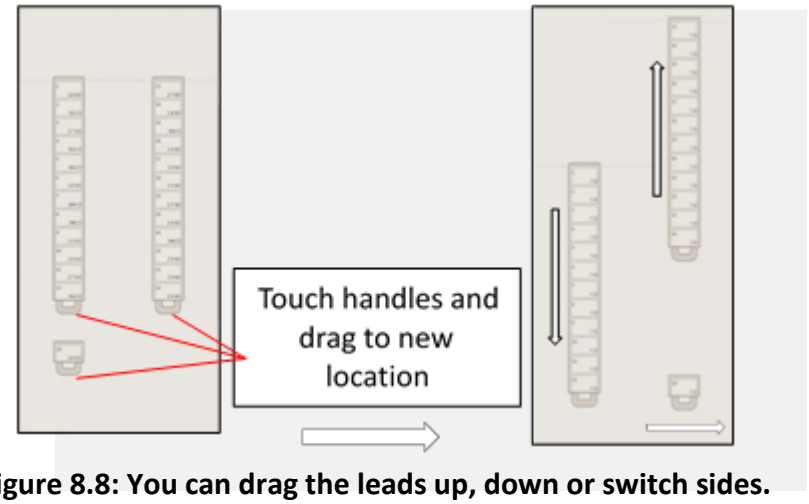
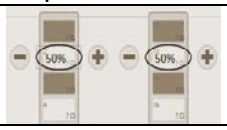
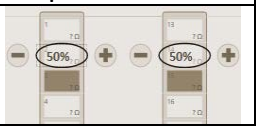
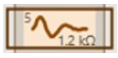


Figure 8.8: You can drag the leads up, down or switch sides.

8.7 Choose the stimulation electrodes automatically

1. Stop stimulation  if stimulation is running.
2. Change the *Electrode Selection Mode* icon (see Figure 8.3 until the *Automatic Electrode Selection* icon  is displayed.
3. 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 9.4).
    - You can also manually change the electrode configuration (see section 9.3).
6. Touch *Set Defaults* icons in the Settings Menu, Stimulation Parameters menu, and Feedback Parameters menu (see **Figure 8.9**) to set standard stimulation parameters.
7. Restart stimulation on the new electrodes.

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

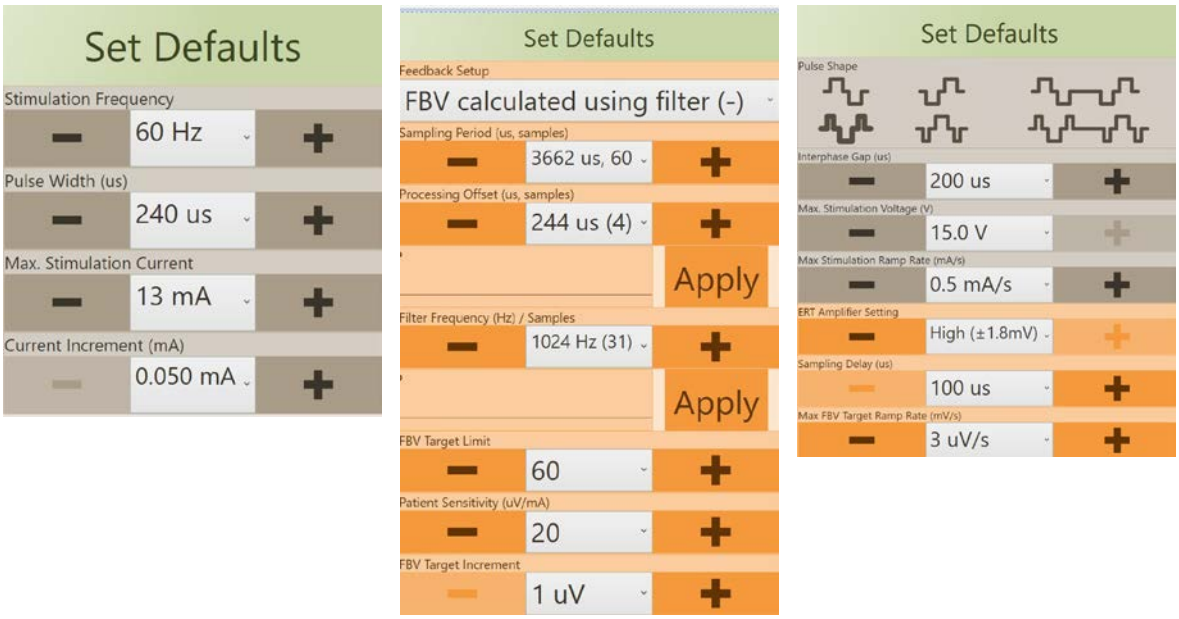


Figure 8.9: Set defaults buttons in the Stimulation settings menu, Feedback Parameters settings menu, and Settings menu.

8.8 Start and stop stimulation

Touch the *Stimulation Settings* icon  to change the stimulation. It will change to show the *Electrode Display* icon  (see Figure 8.10). Changes made to the Stimulation Settings will affect the Stimulation Amplitude Control bar on the right (refer to Figure 8.11 for more details).

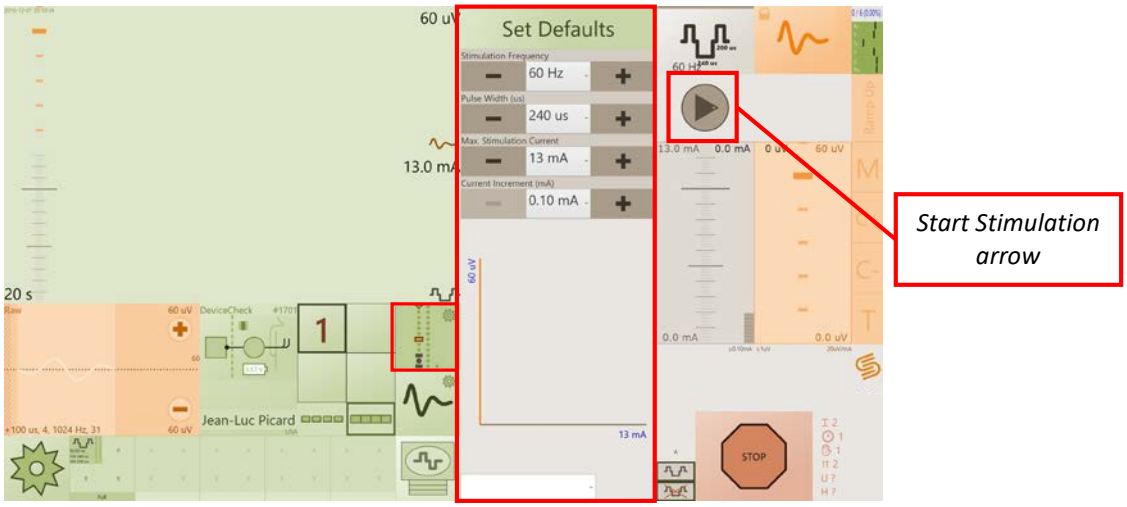
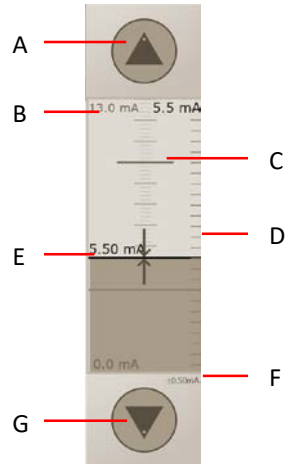


Figure 8.10: Location of the Stimulation Settings Menu and *Start Stimulation* arrow on the CPA.

1. Touch the *Start Stimulation* arrow  (see Figure 8.10).

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 Measurement and Current rolling plot.

2. Touch the *Up* arrow  to increase stimulation current to the desired level (mA).
3. Touch the *Down* arrow  to decrease current.
   Note: The current will increase/decrease by the Current Increment (mA) set. The increment in the current scale is shown on the right side (Figure 8.11D). The scale will extend to the Maximum current set (Figure 8.11B).
4. Press and hold the up or down arrow to change current at a steady rate.
5. Release the button to stop the current from changing.



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

Figure 8.11: Features of the Stimulation Amplitude Control

8.8.1.1 Stop

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

8.9 Set up ECAP measurement

The stimulator records the ECAP signal and displays a graph of the ECAP on the programming screen (Figure 8.12).

Figure 8.12: Location of ECAP display on the CPA.

The ECAP display shows both a single and an averaged ECAP as well as the correlation filter used to measure the Feedback Variable (Figure 8.13). The ECAP display shows the current filter settings and the recommended filter settings, the sampling period, and buttons to zoom in and out of the Y-Scale.

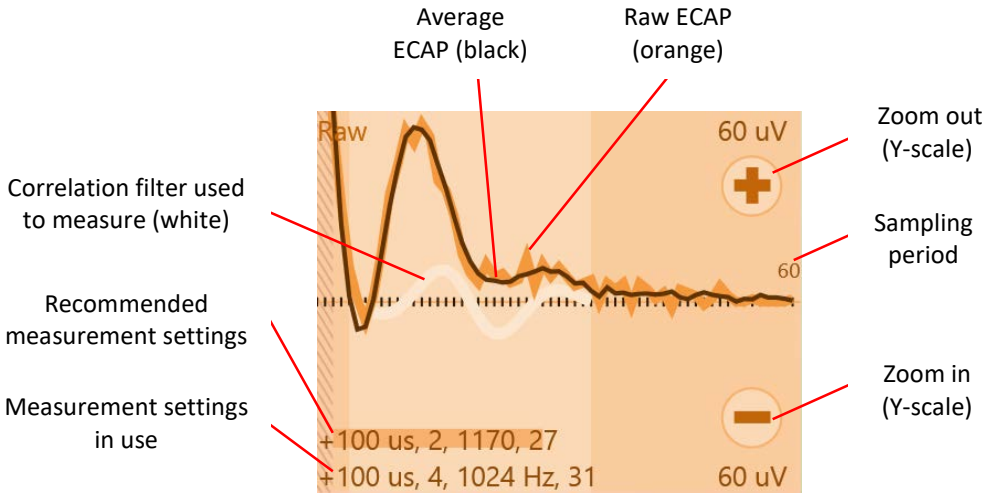


Figure 8.13: ECAP Display.

Note: Measurement settings are, in order: Sampling Delay, Processing Offset (number of samples), filter frequency, and number of filter samples.

1. Touch the *Measurement Settings* icon  to open the 'Measurement and Feedback Settings' menu (Figure 8.14). It will change to show the *Electrode Display* icon  (Figure 8.14C).

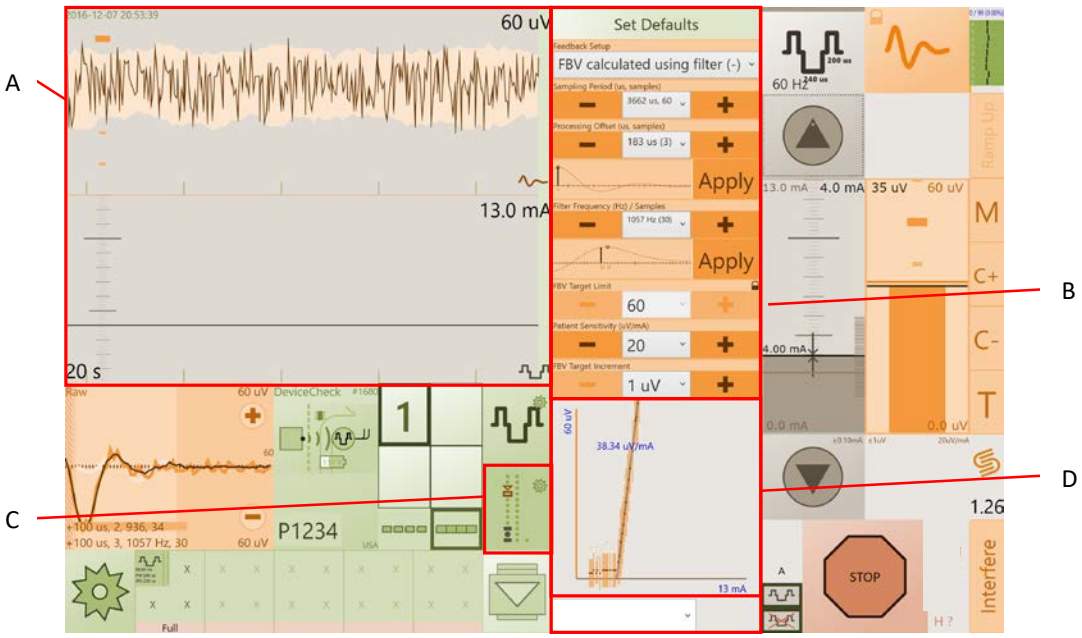
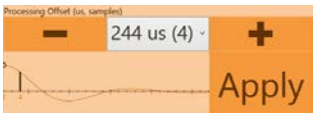
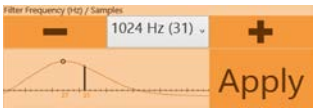


Figure 8.14: Location of the Measurement and Feedback Settings Menu on the CPA.

1. Touch ‘Apply’ to set the optimal Processing Offset 

.
2. Touch ‘Apply’ to set the optimal Filter Frequency 

.
3. The ECAP Measurement and Current rolling plot (Figure 8.14A) displays the ECAP measurement (top) and current (bottom) over time.

8.10 Set up Feedback Control (FC) therapy

The settings for FC therapy vary between patients and for different electrode configurations. Settings can be optimized in the ‘Measurement and Feedback Settings’ menu (Figure 8.14).
The settings for the FC therapy depend on the sensitivity of the ECAP to changes in current. The CPA can measure ECAP sensitivity as the current is varied.

1. Optimize the ECAP measurement.
2. Increase current from near paresthesia threshold to a strong but comfortable level.
3. The *Sensitivity Graph* will display the ECAP size data as a function of current (see Figure 8.15).

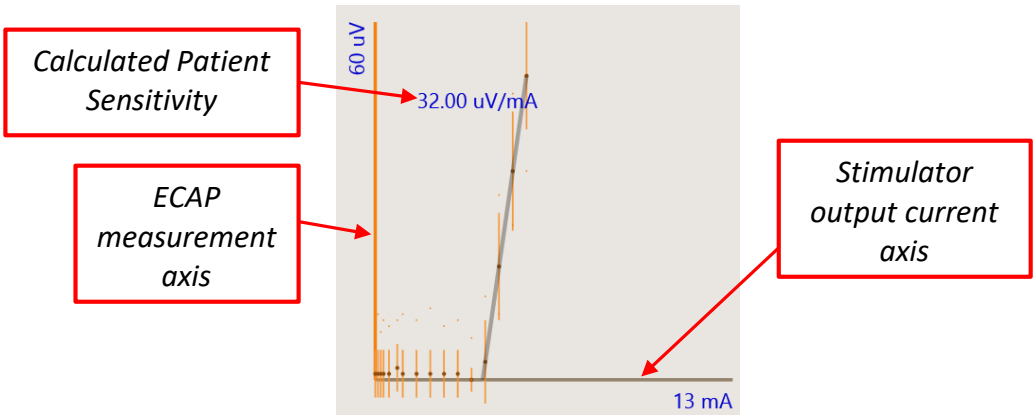


Figure 8.15: The Patient Sensitivity graph – ECAP measurement (µV) versus Current (mA)

4. Enter the calculated value for patient sensitivity  in the *Measurement and Feedback Settings* menu (see Figure 8.14B).

8.11 Enable Feedback Control

Once all the settings for the program have been set up it is important to test the effectiveness of the feedback control.

1. Start stimulation and set the current to a comfortable level.
2. Touch the *FC* icon  to turn FC on (see Feedback Control in Figure 8.3)

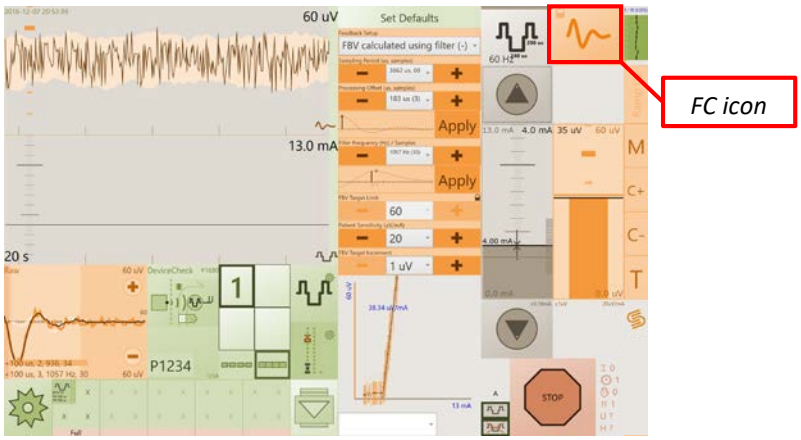


Figure 8.16: Location of the FC icon on the CPA.

3. With FC enabled the rolling plot will now display with an orange background and the current will vary over time (see Figure 8.17). The ECAP measurement will vary around the target level.

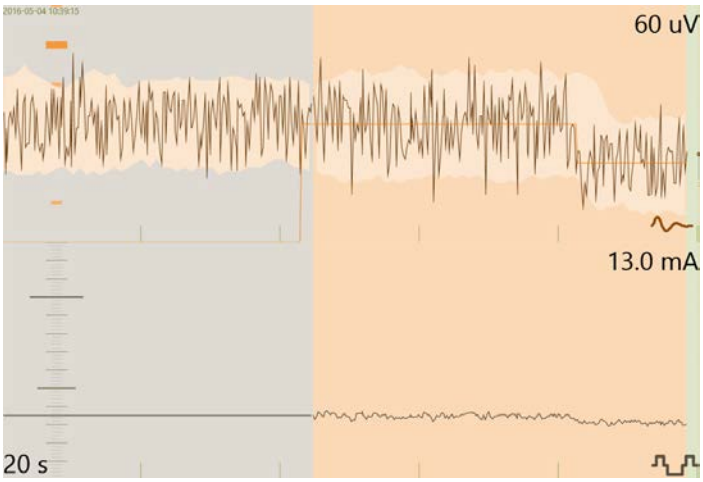


Figure 8.17: ECAP measurement and current rolling plot with FC turned on.

8.12 Save a program to the stimulator

The CLS and eCLS can each hold up to four different programs. The four program windows display the programs currently stored in the CLS or eCLS (see Figure 8.18). Any program that is run on the stimulator (stimulation turned on) is automatically saved to the selected *Program Slot*.

Figure 8.18: Location of the Program Slots and Save Slots on the CPA.

8.12.1.1 To add a new program

1. Touch the desired *Program Slot* (see Figure 8.18), and 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 8.19), and it will be saved to the stimulator.

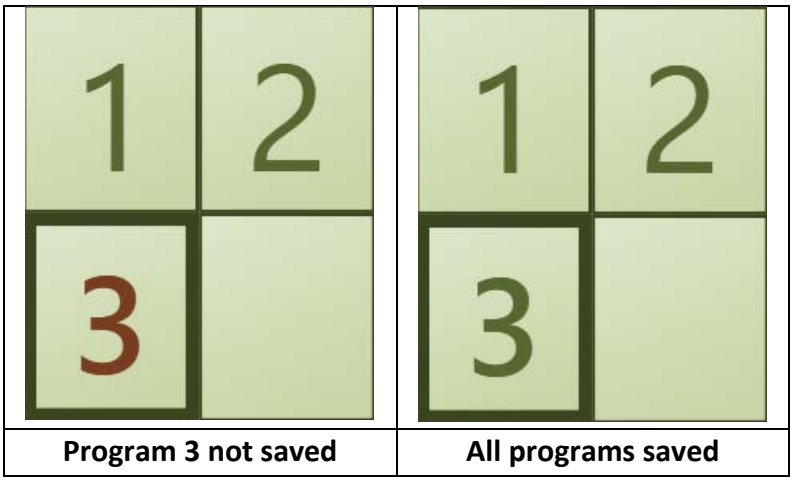


Figure 8.19: (Left) Program 1 and 2 are saved on the stimulator while program 3 is red and has not been run yet; it is not saved to the stimulator. (Right) Program 3 has been run and is now green, all three programs are currently saved on the stimulator.

8.12.1.2 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* before overwriting a program in case you want to restore the previous one.

8.12.1.3 To save a program into the Save Slots

You can create a backup of a program from the stimulator or save a newly created program for later use in the *Save Slots*. This stores a copy of the program as a file on the CI.

1. Touch an empty *Save Slot* to save all the current programs to that slot (see Figure 8.18).

   Note: The programs in the *Save Slots* will only be saved locally to the CI you use to program the patient. If you use more than one programming tablet in your clinic, the programs in the *Save Slots* will not be available on any other CI.

8.12.1.4 To load a previously saved program

To load a saved program into the stimulator:

1. Select the *Program Slot* you want to load the program into.
2. If you want to load a program from a *Save Slot*, go to Step 4; otherwise, if the program file is saved to the CI, go to Step 3.
3. Touch an empty *Save Slot* and choose *Load From File,* locate and select the file then click *Open*.
4. Touch the desired *Save Slot* and choose *Restore*.
   a. You may restore all the programs (up to 4) saved in that slot or a single program of those saved.
5. Turn stimulation on to load the program into the stimulator (individually, for the program(s) that you want to restore). See Figure 8.19 for identifying whether a program has been saved to the stimulator.

8.13 Interleaved Stimulation

A Program may contain several interleaved Stimulation Sets, targeting several areas of pain. The CPA has the ability to run up to four (4) Stimulation Sets per Program, at the same time. Refer to Figure 8.20 below for controls related to interleaved stimulation.

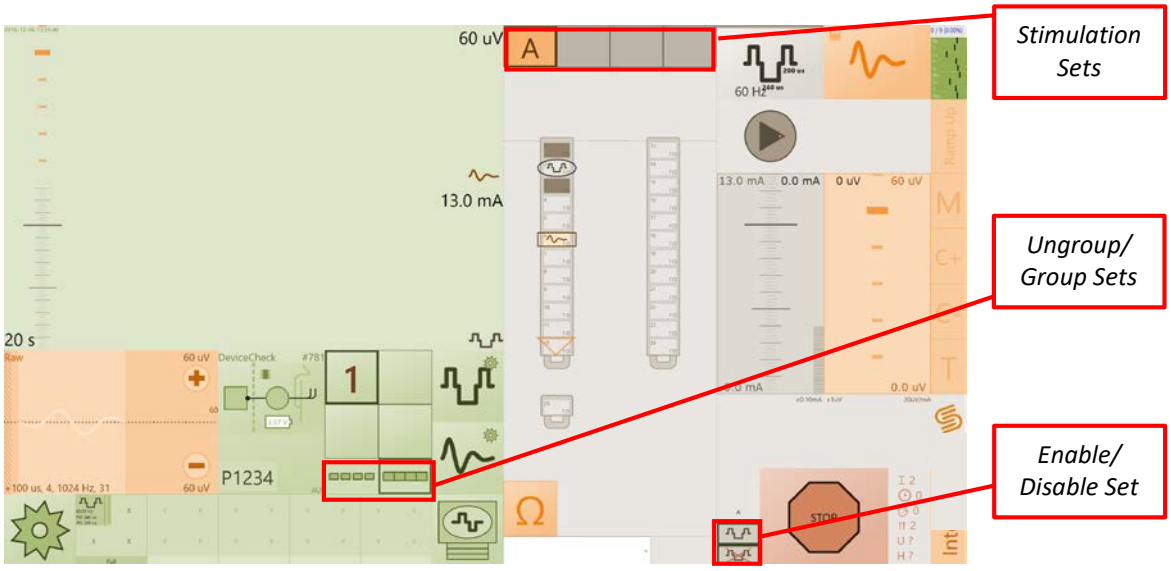


Figure 8.20: Location of controls related to interleaved stimulation in the CPA.

8.13.1 Set up interleaved stimulation

To set up multiple Stimulation Sets in a Program:

1. Select a Program, and Stimulation Set A.
    a. Configure the Program with the desired stimulation and measurement settings (see Sections 8.7 to 8.10).
    b. Measurement is only enabled for Stimulation Set A. The ECAP measurement from Stimulation Set A is used for Feedback Control of all Stimulation Sets.
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 Program with the desired stimulation settings (see Sections 8.7 to 8.8).
    b. 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 8.21) 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 patient preferred level, then stop stimulation.
5. Repeat Step 4 for each remaining Stimulation Set in the Program until all have been set to the patient preferred level (Figure 8.21).
6. Set the Stimulation Sets to run in Grouped mode ( ), start stimulation and increase (all Stimulation Sets) to the patient preferred level.

7. Enable Feedback Control as per Section 8.10.

   Note: Feedback Control will only operate based on the settings in Stimulation Set A (it will vary the current so that the ratio of current between Stimulation Sets remains constant).

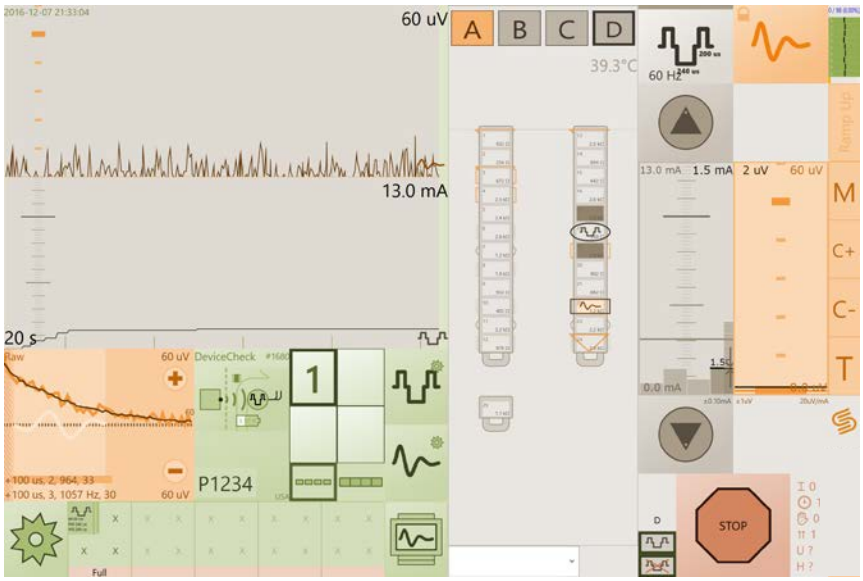


Figure 8.21: A Program with 4 Stimulation Sets configured at desired levels. Note that the electrode settings from all Stimulation Sets are visible in the background while the active set is displayed as normal.

8.13.2 Enable/Disable a Stimulation Set in a Program

To disable a Stimulation Set in a Program:

1. Select the Stimulation Set you want to enable/disable.
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 8.22).

   Note: If a Stimulation Set is disabled () its ratio will be set to 0 and it will need to be reconfigured (refer to section 8.13.3).

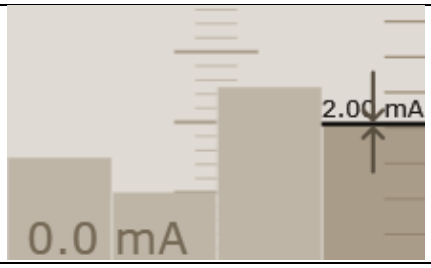
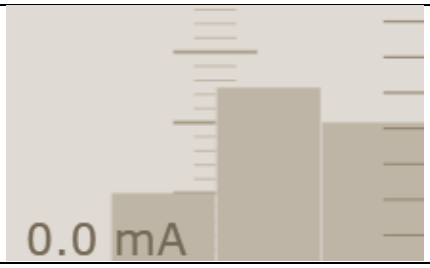
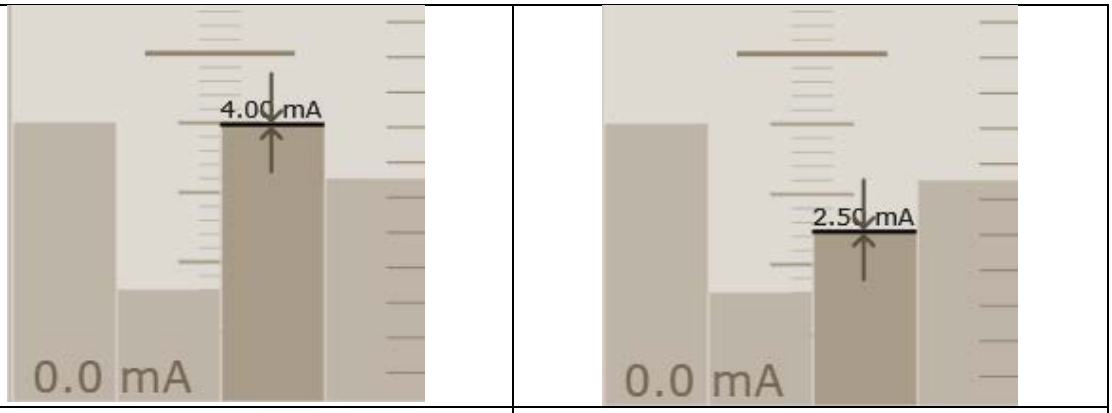
	
All enabled	**Stimulation Set A disabled**

Figure 8.22: (Left) Original current levels with all Stimulation Sets enabled. (Right) Current levels with Stimulation Set A disabled.

8.13.3 Changing the ratio between Stimulation Sets

The ratio between Stimulation Sets can be changed, even during stimulation (Figure 8.23):

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.

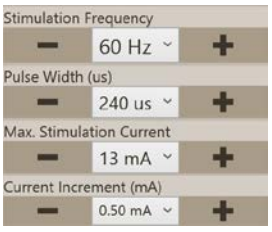


Original ratios, Stimulation Set C selected	Stimulation Set C ratio lowered

Figure 8.23: (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.

9 Clinical Interface – settings guide

9.1 Stimulation Settings Menu



Stimulation Frequency (Hz)	10 – 1500 Hz
Pulse Width	20 – 1000 µs
Maximum stimulation current	1 – 50 mA
Current increment	0.05mA – 4.0mA (depending on the electrode setup)

9.2 Measurement and Feedback Settings Menu

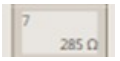
Measurement type	Disabled, Raw data, Filter (+), Filter (-), Amplitude
Sampling period	132 – 10010 µs (2 – 164 samples)
Processing offset	0 – 5981 µs (0 – 60 samples)
Processing Offset graph	ECAP measurement vs. processing offset. Open circle – recommended offset (peak of graph); black line – offset used. Press 'Apply' to use recommended offset
Filter frequency (filter mode	489 – 1928 Hz (66 - 16 samples)
Processing Period (amplitude mode)	61 – 4028 µs (1 – 66 samples)
FBV Target Limit	20 – 10000 µV
Patient Sensitivity	1 – 1000 µV/mA
FBV target increment	1 – 1000 µV

9.3 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 (ERT positive) required and all the other electrodes remain the same. **Note:** Can be changed during stimulation if FC is off.
	**Reference electrode selection**	You select the reference electrode (ERT negative) required and all the other electrodes remain the same. **Note:** Can be changed during stimulation if FC is off.

	**Manual electrode selection**	You select the electrode you wish to change and the electrode will toggle between:

	Stimulation
	Stimulation return
	Measurement – ERT positive (+) input
	Reference – ERT negative (-) input
	Not selected

9.4 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 (Figure 9.1).
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 '-'. The % of current delivered at the other stimulation electrodes will automatically adjust to keep the total at 100%.

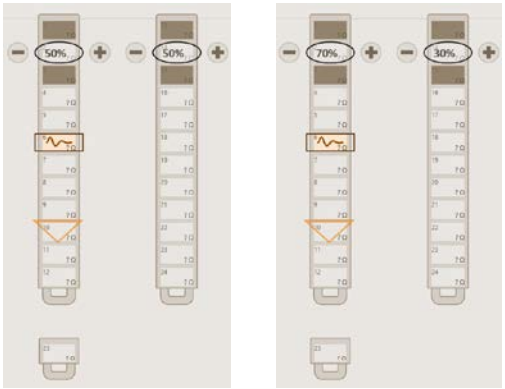


Figure 9.1: Current steering: 50:50% on the left and 70:30% on the right.

9.5 Patient Perception

During programming you may wish to mark the patient's perception levels on the CPA.

1. The 'Threshold', 'Comfort' and 'Maximum' buttons (Figure 9.2) can be used to mark when the stimulation is first felt by the patient, comfortable and very strong, respectively. The levels will be indicated by horizontal lines on the intensity bar graph and on the patient sensitivity graph.

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

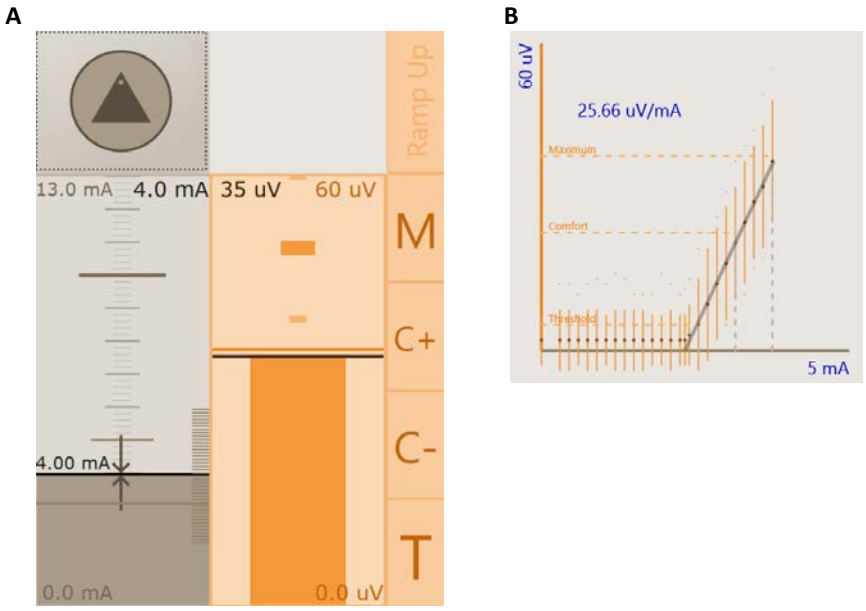
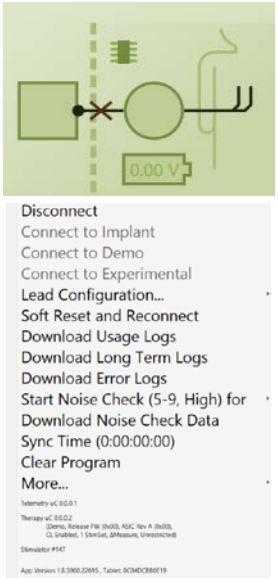


Figure 9.2:A) Patient perception buttons and markers. B) The effect displayed on the Patient Sensitivity graph

9.6 CLS Menu

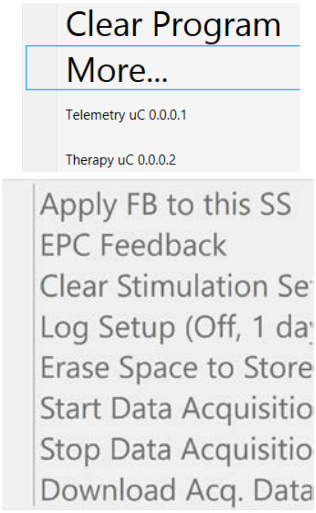
Touch the “CLS icon” for additional CLS and eCLS functions.



Connect to Implant	Search and connect CPA to stimulator.
Connect to Demo	Run in Demonstration mode. Normal operation connected to a simulated (demo) stimulator
Connect to Experimental	Run in Experimental mode. Operation with new features connected to a simulated (demo) stimulator
Lead Configuration	To switch between different lead types (12C percutaneous, 12C paddle, 24C paddle)
Soft Reset and Reconnect	Reset stimulator, clear Safe Mode errors and reconnect.
Download Usage Logs from Stimulator	Download usage logs from stimulator.
Download Error Logs from Stimulator	Download error logs from stimulator.
Download Long Term Logs	Download therapy logs from stimulator.
Start Noise Check (0-5, High)	Start noise check.

Download Noise Check Data	Download noise check data from stimulator.
Synchronize Stimulator Time	Synchronize stimulator time with CI.
Clear Program	Clear the selected program from the stimulator.
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.

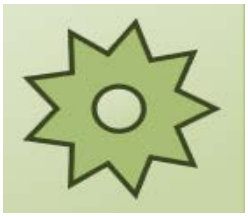
Touch the ‘More…’ field for the next menu.



EPC Feedback	Allow the ability to enable/disable Feedback Control using the EPC.
Clear Stimulation Set	Clear active stimulation set.
Log Setup	Set up therapy log settings.
Apply FB to this SS	Select current stimulation set
Erase Space to Store Acquired Data	Configure memory for data acquisition.
Start Data Acquisition	Acquire data.
Stop Data Acquisition	Stop acquiring data
Download Acquired Data from Stimulator	Download acquired data from stimulator

9.7 Settings Menu

Touch the “Settings icon” for additional CPA functions.



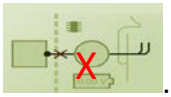
Return to Main Screen	Close Settings Menu and return to CLS screen.
Stop	Stop stimulation
Exit Application	Close CPA – stimulation will continue if on
Engineering Information	Used by Saluda Medical staff to obtain device related information.
Pulse shape	Biphasic - Positive first, Negative first, Alternating Triphasic - Positive first, Negative first, Alternating

Interphase Gap	20 – 500 µs
Maximum stimulation voltage	7.5 – 15 V
CPA – current ramp rate	0.05 – 5.0 mA/s
NRT amplifier gain	High (± 1.8 mV), Low (± 7.2 mV)
Sampling delay	100 – 1000 µs
CPA – FBV target ramp rate	1 – 200 µV/s
Factory Reset and Reconnect	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.

9.8 Error Display

When errors occur they will be displayed over the ECAP Measurement and Current rolling plot (Figure 9.3). A count of the errors from the error log are also displayed to the right of the Stop button (see Table 9.1 for more information regarding the symbols).

9.8.1 Safe Mode Errors

A red cross in the CLS icon indicates a safe mode error  .

1. Use the CPA to reset the CLS out of Safe Mode (see *Soft Reset and Reconnect* in section 9.6).
2. Contact Saluda Medical to report the occurrence of the error code displayed.

Figure 9.3: Error display and error counts on the CPA screen.

Table 9.1: Error count symbol information. Note that a '?' means log was not downloaded or that an error occurred during download, stop stimulation and download the log again.

Symbol	Description
I 0	ERT Clipping count
0	Clock Error count
2	Magnet Reed Switch count
1	Current at Max count
U ?	If present, then Usage Log did not download or there was an error
H ?	If present, then Long Term Log did not download or there was an error

For more information regarding how the stimulator responds to errors see section 10.

10 Operation of stimulator when errors occur

Refer to Section 9.8 for error display on the CPA.

10.1 Out of Compliance

Out of Compliance (OOC) occurs when the stimulator is unable to achieve the desired current level as the voltage requirement exceeds the Maximum Stimulation Voltage (see section 9.7). When OOC is indicated the stimulator checks the connection of each stimulation electrode:

1. If any stimulation electrodes are disconnected, then stimulation stops.
2. Otherwise stimulation will continue but current can only be decreased until OOC is no longer indicated.

10.2 Reference Clock Error

A reference clock error is an indication that the timing used to generate the stimulation pulse is incorrect. During stimulation, the firmware shall monitor for a reference clock error every stimulation period, and will disable Feedback Control (open loop mode) for that period. If more than one Reference Clock Error occurs in seven consecutive stimuli, then stimulation will stop.

10.3 Electrode Disconnected

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

10.4 Current at Maximum

In closed loop mode, if the stimulation current is at its maximum setting, the stimulator checks the connection of the recording electrodes:

1. If one or more recording electrodes are disconnected, the stimulation stops.
2. Otherwise: stimulation continues, but the FBV target halved. Then:
    a. If the measured ECAP is greater than the new target, then the stimulator shall continue in Feedback mode.
    b. If the measured ECAP is less than the new target (indicating a potential problem with ECAP measurement), the stimulator will stop stimulation and enter open loop mode. When stimulation is restarted by the patient the stimulator will return to closed loop mode when the measured FBV exceeds the target.

10.5 ERT Clipping

When in closed loop mode, for each stimulus, the stimulator checks the ECAP signal is within the ERT Amplifier Setting limits (see section 9.7). If ERT Clipping occurs, the stimulus current for the next stimulation event will not be updated. If ERT Clipping occurs for 4 consecutive stimuli, stimulation stops.

11 Evoke™ Pocket Console and Evoke™ Charger

Note: Full details on the use of the Evoke™ Pocket Console (EPC) and the Evoke™ Charger are available in the Evoke™ User Manual.

11.1 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  at the same time for more than 1 second to enter *Pairing* mode.
    - While searching for the stimulator, the EPC will buzz every 0.5 seconds for 10 seconds.
    - The EPC will beep one time (one long beep) if pairing is successful
    - The EPC will beep three times if pairing is unsuccessful because no stimulator was detected.
    - The EPC will beep four times if pairing is unsuccessful because more than one stimulator has been detected.
    - Press  to start using the EPC, or to start searching again if pairing was unsuccessful,

11.1.1Un-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 11.1.

Note: You do not need to un-pair the EPC from the stimulator it is already connected to before pairing it to a new one.

12 Evoke™ Charger

Refer to the Evoke™ User Manual for instructions on using the Charger.

12.1 Safe Mode Error on Charger

If the patient reports that their Charger detects that the CLS is in Safe Mode (*Contact Clinician* indicator lit) then the CLS cannot be charged normally.

1. Ask the patient to visit the clinic so that the error can be investigated and the CLS reset out of Safe Mode.
2. See section 9.8.1 Safe Mode Errors and section 9.6 *Soft Reset and Reconnect* to reset the CLS out of Safe Mode.
3. If the CLS has a depleted battery and cannot communicate with the CI, then contact your Saluda Medical Representative to charge the CLS battery.

13 Patient ID Card

Every CLS is supplied with a Patient ID Card for the surgeon to complete.
Give the Patient ID Card to the patient so that they can use it to show other medical practitioners or security personnel that they have an implanted device.

14 Maintenance of the Evoke™ CI and Evoke™ CST

14.1 Maintenance of the Evoke™ CI

Maintenance of the Clinical Interface should be carried out according to instructions in the Surface Pro 4 manual accessible at https://www.microsoft.com/surface/en-au/support/browse/surface-pro-4.

14.2 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

15 Specifications

15.1 Evoke™ CI

Full specifications for the Clinical Interface hardware can be found in the Surface Pro 4 manual accessible at https://www.microsoft.com/surface/en-au/support/browse/surface-pro-4.

15.2 Evoke™ CST

Table 15.1: Evoke™ CST.

Dimensions	Length – 85mm, Width – 53mm, Depth – 16mm
Material	Top and bottom cases - ABS (UL94HB) Intermediate Ring – TPE (SEBS)
IP Rating	IP54
Communications Link	USB connection between laptop and transceiver module MICS band radio to CLS/eCLS: Microsemi ZL70102
Storage Temperature Limitations	Low: -20 °C (-4 °F) High: 60 °C (140 °F)

15.3 Evoke™ CLS

Table 15.2: Evoke™ CLS.

Materials	Case	Titanium
	Header	Epoxy
	Seals	Liquid silicone rubber
	Connector springs	Platinum Iridium (24 x connectors)
	Set screw	Stainless steel
Dimensions	68 mm x 48 mm x 12 mm (2.7 in x 1.9 in x 0.472 in)	
Volume	33 cm^3 (2 in^3)	
Weight	50 g (1.76 oz.)	
Lead ports	2 Each percutaneous lead is secured by a set screw at the port entry	
Electrodes	25	Port 1: electrodes 1-12 Port 2: electrodes 13-24 CLS case is electrode 25
Stimulation parameters	Current	0 mA – 50 mA (default 0 mA)
	Pulse Width	20 µs – 1000 µs (default 120 µs)
	Frequency	2 Hz – 1500 Hz (default 60 Hz)
Radio frequency communication	MICS band	403 MHz
	Range	1.0 m (3.3 ft.)
Battery	Battery type	200 mAh Li-Ion rechargeable battery
	Battery life	Greater than 10 years at moderate settings (current = 5.0 mA, pulse width = 200 µs, frequency = 60 Hz, impedance = 750 Ω, 24hrs/day usage)
Charging	Transcutaneous charging using inductive coupling with an external coil	
	Implant depth	5 mm to 20 mm (0.2 in to 0.8 in)
Recording amplifier gain	Low: 250x High: 1000x	
Data recording	32 MB, up to 1 year (Stimulation usage, ECAP amplitude and current statistics)	
Radio opaque identifier	“SME AYY” Where “SME” is Saluda Medical, “A” is the CLS model and YY is the two-digit year of manufacture	

15.4 Evoke™ eCLS

Table 15.3: Evoke™ eCLS.

Materials	Case	Nylon 12
	Plug / socket	TPE
	Cable	TPE
Dimensions	85 mm x 78 mm x 16 mm (3.35 in x 3.07 in x 0.63 in)	
Weight	124 g (4.4 oz.)	
Battery	Same as the CLS (See Section 15.1)	
Functional specifications	All functional specifications are the same as for the CLS (See Section 15.1), with the exception of the following	
Electrodes	24	Port 1: electrodes 1-24
Charging	Charging using inductive coupling with an external coil	
IP Rating	IP22	
Storage Temperature Limitations	Low: -20°C (-4F) High: 60C (140F)	

15.5 Evoke™ 12C Percutaneous Lead

Table 15.4: Evoke™ Percutaneous Lead.

Materials	Lead body	Pellethane
	Lead ends	Pellethane and epoxy
	Distal electrodes	Platinum Iridium
	Proximal connectors	Platinum Iridium
	Retention ring	MP35N
	Conductors	MP35N with Ag core (19 strand cable)
Dimensions	Lengths	60 cm (1.97 ft.) or 90 cm (2.95 ft.)
	Diameter	1.32 mm (0.05 in)
Electrodes	Number	12
	Length	3 mm (0.12 in)
	Pitch	7 mm (0.276 in)
Connectors	Length	1 mm (0.039 in)
	Pitch	1.96 mm (0.077 in) center to center

16 Glossary and Symbols

16.1 Glossary

Table 16.1: Glossary

Term	Definition
Charger	The device that charges the battery in the CLS/eCLS
Clinical Interface (CI)	The computer loaded with the CPA used to program the CLS/eCLS
Closed Loop Stimulator (CLS)	An implantable pulse generator capable of feedback control (aka Closed-loop mode)
Clinical System Transceiver (CST)	Exchanges information between the CI and the CLS/eCLS
Clinical Programming Application (CPA)	A computer program user interface that provides the functionalities required to program and analyze the performance of the CLS/eCLS
Electrode	An electrical contact that may be employed to deliver therapeutic current, measure neural responses or control closed-loop stimulation.
Evoke™ Pocket Console (EPC)	A remote controller that allows the patient to adjust the therapy output from the CLS/eCLS
Evoked Compound Action Potential (ECAP)	The sum of electrical signals elicited by a stimulus from multiple nerve fibers.
External Closed Loop Simulator (eCLS)	The eCLS is a non-implantable device with the same functionalities as the CLS
Feedback Control (FC)	The automatic adjustment of stimulation output in response to a measured ECAP
Interphase Gap (IPG)	The delay between phases of a stimulation pulse
Program	The complete set of parameters describing stimulation, recording, measurement and feedback. A program may contain up to 4 Stimulation Sets.
Stimulation Set	A set of stimulation parameters designed to target a particular area of the Clinical Subject's pain.
Lead	Insulated cable with a number of exposed electrodes at the distal end used in neurostimulation therapy
Spinal Cord Stimulation (SCS)	A treatment for chronic pain utilizing pulsed electrical signals delivered to the spinal cord
Lead Adapter	Sterilized cable which enables the connection between leads/lead extensions and the eCLS

Lead Adapter Extension	An extension cable which allows for a longer length of cable between eCLS and lead/lead extensions
Lead Extension	Insulated cable which connects to the proximal end of a lead and in turn connects to either a CLS or eCLS

16.2 Symbols

Table 16.2: Symbols

Symbol	Definition
 or 	Consult instructions for use
	Catalogue number
	Serial number
	Lot number
 YYYY-MM-DD	Use by date (YYYY = year, MM = month, DD = day)
	Caution
	Caution – Refer to Instructions for Use at www.saludamedical.com/manuals
	Refer to Instruction for Use at www.saludamedical.com/manuals
	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
	Sterilized using ethylene oxide
	Do not re-sterilize
	Do not re-use
	Power supply connection

	Serial interface

17 Contact us

Most questions you have about the Evoke™ Closed Loop Stimulator and its accessories 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 field clinical engineer (FCE). Alternatively, you can contact us via the details below or email us at info@saludamedical.com.

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