



Evoke® SCS System User Manual

Instructions for the use of the Evoke SCS System

Rx Only

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1 Description

This User Manual is intended for patients who have received the Saluda® Medical Evoke® SCS System for either a temporary trial or as a fully implanted system.

The Evoke SCS System is a closed-loop spinal cord stimulation (SCS) system that is intended to be used to treat chronic pain of the trunk and/or limbs. It stimulates the nerves in your spinal cord, measures their responses, and can automatically adjust the stimulation level accordingly.

Before receiving a fully implanted system, you will go through a temporary trial period where you and your doctor can evaluate the system. If you and your doctor feel that the Evoke SCS System is right for you, you may decide to move to a fully implanted system.

The Evoke SCS System comprises several key parts to deliver your therapy:

- **Evoke External Closed-Loop Stimulator (eCLS).** During the trial stimulation period, your percutaneous leads will be connected to the Evoke eCLS. The eCLS is an external stimulator that you wear during your trial stimulation period. The eCLS delivers automatic or manually controlled therapy through your percutaneous leads. The eCLS has a removable battery which is charged by a clinician or Saluda Medical representative.
- **Evoke Closed-Loop Stimulator (CLS).** The Evoke CLS is a totally implanted spinal cord stimulator that connects to your percutaneous leads and is implanted under the skin for long-term therapy. The CLS delivers automatic or manually controlled therapy through your percutaneous leads.
- **Evoke 12C Percutaneous Leads.** The Evoke 12C Percutaneous Leads are placed in the epidural space overlying your spinal cord and are connected to the eCLS for a trial period, or permanently implanted and connected to the CLS for long-term therapy. You may have 1 or 2 percutaneous leads implanted, and there are 12 electrodes on each lead. This gives your clinician the ability to find the stimulation settings that best give you pain relief.
- **Evoke 12C Lead Extensions.** The Evoke 12C Lead Extensions may be used during the trial period to connect your leads to the eCLS. Your surgeon will determine if lead extensions are required.
- **Evoke Patient Controller (EPC).** The EPC allows you to control your therapy and monitor your stimulator (either a CLS or eCLS). The EPC and the stimulator communicate with each other wirelessly. The EPC kit also includes a magnet, which allows you to stop stimulation from the CLS or eCLS without using the EPC.
- **Evoke Charger.** The Evoke Charger allows you to recharge the battery in your stimulator (CLS). The Charger coil (attached to the Charger) is placed on clothing covering the skin over the implanted CLS and charge is transferred wirelessly to the CLS. The Charger is battery operated, and a power adapter is included in the kit for recharging the battery in the Charger.

- **Evoke Accessory Belt.** The Evoke accessory belt is an elasticated belt with a pouch that you wear to hold either the eCLS or Charger coil in place.

2 Indications for use – What the Evoke System is used for

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 – When the Evoke System must not be used

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.

4.1 Warnings

Diathermy

- You should not be subjected to shortwave, microwave and/or therapeutic ultrasound diathermy.
- Diathermy generates energy that may cause heating at the lead site, resulting in tissue damage, severe injury, or death.
- It may also cause damage to the CLS and you may need surgery to replace it.

Magnetic Resonance Imaging (MRI) scans



The Evoke System is considered MR Unsafe, as the safety of this system within an MRI environment has not been tested.

- Under no circumstances should you have an MRI scan while you have the Evoke System.

- Having an MRI scans while you have the Evoke SCS System may:
 - Cause significant heating resulting in tissue damage and/or severe injury.
 - Damage the CLS and you may need surgery to replace it.
 - Cause unintended stimulation such as tingling, shocking or jolting.
- If an MRI scan is suggested for you, it is important that you inform the clinician recommending the MRI scan that you have an implanted SCS system that is considered MR Unsafe.
- It is also important that you tell your doctor who looks after you in relation to your stimulator, if an MRI scan is suggested for you.

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.
- You should turn your stimulator off before undergoing a CT scan.

Implanted cardiac pacemakers or defibrillators may be affected by your Evoke System

- You should not use your Evoke System if you have any implanted cardiac devices, due to interference between them.
- The effect of other implanted stimulators on your Evoke System is unknown. We recommend that you should consult your doctor before undergoing implantation of other medical devices.

Strong electromagnetic fields may cause you discomfort

- Avoid strong electromagnetic fields as they may cause your stimulator to switch off, cause an uncomfortable or jolting sensation, or affect communication with your EPC.
- Your stimulator may be affected by:
 - Security screeners such as those used at department stores, public buildings, and airports.
 - Present your Patient ID card and request to go around the screener.
 - Turn stimulation off if you are required to go through the scanner.
 - Power cables and generators.
 - Electric arc-welding devices and electric steel smelters.
 - Audio speakers that contain strong magnets.
 - Anti-theft devices used in shops and libraries.
 - Radio communication transmitters or antennas, such as CB radio antennas (see Section 15.3).

- If you feel an effect in your stimulation from an electromagnetic field, turn off your stimulator and move out of the space as quickly as you can.
- Discuss with your doctor before entering any area that may affect how your stimulator works, including areas displaying a warning notice preventing entry by patients fitted with a pacemaker.

 **You should not charge the stimulator while sleeping, or with the Charger or Charger coil against your skin.**

- The Charger, Charger coil and/or CLS may become hot during charging.
- If you lie on or lean against the Charger or Charger coil, it may heat up enough to cause skin redness, skin irritation or a burn.
- Ensure there are no metal objects between the Charger coil and the stimulator during charging, as the metal object may heat up and cause skin redness, skin irritation or a burn. Additionally, the Charger may not operate correctly.
- The Charger unit may become hot during use, with a surface temperature reaching 48 °C (118 °F). Do not hold the Charger unit for longer than 10 minutes during use to prevent risk of skin irritation, redness or injury.
- If you experience pain or discomfort during charging, you should stop and contact your clinician.

 **Before any other surgical procedures, notify your clinician or dentist that you have an implanted stimulator**

- Some surgical procedures use electrical current that could affect your implanted stimulator and leads, cause serious injury to you, and/or may damage your stimulator.
- Before any procedure, tell your clinician that you have an implanted stimulator, so they can conduct the procedure without using electric current near your implanted stimulator or leads.

 **If you may be allergic to parts of the stimulation system you should not be implanted with a stimulator**

- If you are allergic to some metals or plastics, please notify your clinician so that they can check whether the items you are allergic to are used in the stimulation system.

 **Cables and small parts**

- The cables in this system pose a strangulation risk. To avoid strangulation, be careful when using cables and keep out of the reach of children.
- Small parts and accessories could be hazardous if swallowed or cause choking if ingested or inhaled. Keep small parts and accessories out of the reach of children.

 **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

 **You must inform your clinician that you have an implanted stimulator before undertaking other treatments. Ask your clinician to refer to the Evoke SCS System Surgical Guide for information on precautions to follow for the following treatments:**

- Lithotripsy, which uses sound waves to disintegrate gallstones and kidney stones.
- Electrocautery or electrosurgery, which uses an electric current to cut tissue and stop bleeding during surgery.
- External defibrillation, which uses a strong electric shock to the chest wall to restore rhythm to the heart.
- Radiation therapy or radiotherapy, which uses ionising radiation, usually to control or kill malignant cancer cells.
- Ultrasound and Doppler ultrasound, which use very high frequency sound waves to create images of your internal organs or to monitor the state of a pregnancy.
- High intensity ultrasound, which uses very high frequency sound waves to create heat inside bones or muscle.
- Transcutaneous electrical nerve stimulation (TENS), which uses electric current to stimulate nerves for therapeutic purposes.
- Psychotherapeutic procedures such as Transcranial Magnetic Stimulation or Electroconvulsive Therapy.
- Laser procedures.

Operating equipment

The Evoke System is a SCS system that measures the patient's Evoked Compound Action Potential (ECAP) in response to stimulation and adjusts the amplitude of stimulation in order to maintain stable coverage of painful areas. This is known as ECAP-controlled closed-loop stimulation.

When the stimulator is operating with closed-loop stimulation enabled:

- You may leave stimulation on while operating automobiles, other vehicles, or potentially dangerous equipment.
- If you are charging the stimulator, closed-loop is disabled, so you should turn stimulation off if charging while driving or operating equipment.

- If you ever experience sudden changes in stimulation with closed-loop enabled, you should turn stimulation off before driving or operating equipment. In this case, you should contact the clinic to reprogram the closed-loop settings in the stimulator.

If the stimulator is operating with closed-loop stimulation disabled:

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



Be especially careful in the six to eight weeks after your surgery

- In the first six to eight week after your surgery, your body will still be healing from the surgery, and the implant or leads may move with some activities.
- Do not lift heavy objects greater than 11 lb. (5 kg).
- Try to limit bending, stretching or twisting as much as possible.
- Try to avoid raising your arms above your head repetitively.
- You may experience temporary pain at the implant site as the incisions heal after the surgery.
- If you notice redness or feel irritation at the wound site, contact your clinician to check for infection.



Do not try to move your stimulator by pushing it under your skin

- It is normal to be able to feel the stimulator under your skin – do not try to move it or relocate it by pushing or massaging your skin.
- If you move your stimulator, it may flip over and you will not be able to charge it.
- Moving the stimulator may damage the leads or cause pain, irritation or thinning of the skin over the stimulator.



Scuba diving

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



If you suspect part of your system is not working properly

If you are having problems with your system, first consult Section 13 ‘Troubleshooting’. If this does not help or you have more questions, please contact your clinician.

 Do not modify or tamper

- Do not modify or tamper with your Evoke Patient Controller (EPC), your Charger or your external Closed-Loop Stimulator (eCLS, if you have been given one). Modifying or tampering with your equipment could cause these items not to work at all, or to operate in an unpredictable way. This could lead to a loss of therapy.
- Do not connect anything to the eCLS or Charger that is not supplied as part of the Evoke System. The Charger should only be connected to the supplied power adapter. Only your clinician should connect the eCLS to lead adapters and recharge or replace the eCLS battery (refer to Section 5.5.1 'Using the eCLS'). Connecting these devices to other, unsupported items could damage them and lead to a loss of therapy.

 Protect the eCLS, EPC and Charger from extreme heat, cold or humidity

The electronics in your devices can be damaged by extreme heat, cold and humidity.

- Do not leave your devices in your car or outdoors for extended periods of time.
- Do not store your devices in humid environments, such as the bathroom.
- Avoid storing the eCLS at temperatures below 14 °F (-10°C) or above 131 °F (55 °C).
- Avoid storing the EPC and Charger at temperatures below -4 °F (-20 °C) or above 140 °F (60 °C).
- Allow your devices to reach room temperature for 30 minutes before use if they have been stored in cold or warm conditions.
- Only use the eCLS and EPC at room temperatures of 41 °F (5 °C) to 104 °F (40 °C).
- Only use the Charger at room temperatures of 41 °F (5 °C) to 86 °F (30 °C). Do not use the Charger if the room temperature is above 86 °F (30 °C).
- Do not open the eCLS case to avoid exposing the eCLS to damaging moisture or humidity.

 Treat your eCLS, EPC and Charger gently

- Carry and hold your accessories carefully to protect them from striking hard surfaces or being dropped.
- Try to keep your accessories dry, and never immerse them in water.
- Do not plug the Charger into outlets that are in humid environments – such as a bathroom – or near water.
- Ensure you can always access your EPC and keep a spare set of AAA batteries at home for the EPC.
- Be sure to plug in the power adapter for the Charger somewhere easy to access.

- If you need to clean your accessories, refer to Section 10 ‘Maintenance of EPC, Charger and eCLS’.
- The Serial connection  on the Charger is for Saluda Medical representative use only. This connection is protected by a silicone plug. Ensure the plug is fully inserted at all times.

Device malfunction or failure

If any of your devices, including your eCLS, EPC and, Charger, are damaged, malfunction, fail, become uncomfortably hot, emit smoke or a strange smell, switch the device off immediately, stop use and contact your clinical team.

- Continued use of damaged or malfunctioning devices may cause electrocution, burns, contact with hazardous chemicals, or uncomfortable stimulation.
- Please contact your clinician in the event of any device malfunction or failure.

Battery Care

The EPC is powered by two disposable AAA alkaline batteries. Observe the following guidelines for safe use of batteries with your EPC:

- Insert batteries in the correct orientation by observing the plus (+) and minus (-) marks on the batteries and the EPC.
- Do not mix batteries that differ by manufacturer, brand, type, age or previous usage.
- Replace both batteries at the same time.
- Do not touch the battery contacts in the EPC.
- Do not short-circuit batteries (e.g. do not let terminals of batteries contact each other, do not place batteries loose in pockets, etc.).
- Do not disassemble, deform, immerse in water, or dispose of batteries in fire.
- Wipe batteries with a clean dry cloth if they become dirty.
- Store unused batteries in original packaging, in a clean and dry place.
- Do not use damaged or deformed batteries. If skin or eyes come into contact with battery fluid or liquid, wash out with water and seek medical attention immediately.
- Do not expose batteries to heat (e.g. never leave batteries in sunlight, behind a window or in a car).
- Do not recharge batteries.
- Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep away from children.

The Charger is powered by internal rechargeable lithium ion batteries that you cannot replace.

- Only use the power adapter supplied by Saluda Medical to recharge the Charger.
- Do not touch the power adapter socket on the Charger.
- Do not leave the Charger power adapter plugged in after recharging is complete.

The eCLS is powered by a rechargeable lithium ion battery that can be recharged or replaced only by your clinician or a Saluda Medical representative.

- Do not open the case of your eCLS, remove or tamper with the eCLS battery.
- Please contact your clinic for recharge or replacement of your eCLS battery.

Disposal of your stimulator, EPC and Charger

- Your eCLS, EPC and Charger should be returned to your physician if you are no longer using them.
- Your eCLS, EPC and Charger contain batteries that could explode if they are thrown into a fire.

4.3 Potential risks or side effects

All medical procedures involve some risk of injury, including death. In addition, there may be risks associated with having a SCS system that are presently unknown or unforeseeable. Despite all reasonable precautions, you might develop medical complications from having a SCS system.

Potential risks of implantation and use of a SCS system

- Undesirable changes in stimulation sensation and/or location.
- Uncomfortable changes in stimulation (over and/or under stimulation).
- Temporary or persistent post-surgical pain at hardware implantation sites.
- CLS migration or sub-optimal placement, which may result in pain or difficulty in charging.
- Seroma or hematoma at surgery sites.
- Epidural hemorrhage, spinal cord injury, possible paralysis or other neurological complications.
- Lead migration or sub-optimal placement, which may result in undesirable stimulation changes.
- Breakage of the lead, or malfunction or failure of other system components, which may result in undesirable changes or loss of stimulation.
- Allergic response or tissue reaction to the implanted or external materials.
- Infection that may require hospitalization with intravenous antibiotic therapy.
- Infection that may result in epidural abscess that can lead to neurological harm.
- Cerebrospinal fluid (CSF) leakage with possible fistula formation.

- Gastrointestinal and/or genitourinary disruption or compromise.
- Inadequate pain relief following system implantation or over time.
- Erosion of the implanted components through the skin.
- Weakness, clumsiness, numbness, abnormal sensations or pain.
- Skin irritation.

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

5 Temporary trial stimulation

To test whether you will get a benefit from the Evoke spinal cord stimulation therapy, you may have a temporary trial stimulation period.

- The trial usually lasts for up to a week, although some trials may last up to 30 days.
- During this trial stimulation period, you will have one or two 12C percutaneous leads implanted in your spine by your clinician in a minor surgical procedure. Your surgeon may also connect the leads to 12C lead extensions if required.
- After the surgery, the leads or lead extensions will be connected to an External Closed-Loop Stimulator (eCLS) to deliver stimulation pulses through your leads to your spine.
 - Your eCLS will be supplied fully charged. If the eCLS battery becomes depleted, please return to your clinic for battery recharge or replacement.
- You will control the eCLS with the Evoke Patient Controller (EPC).

5.1 Percutaneous lead placement procedure

The leads will be implanted in your back near your spinal cord:

- In this procedure, you will lie face down, awake but sedated.
- Your skin will be cleaned and anesthetized with a local anesthetic.
- The surgeon will slide a small needle in your spine.
- A lead is inserted through the needle near the spinal cord.
- The surgeon may elect to turn the stimulation on to take recordings from your spinal cord, or to test the stimulation, to make sure it is in the correct place in your back. You may feel stimulation pulses (tingling) in various areas of your body at this time.
- The surgeon may move the lead to get a better position.
- This process is repeated if you require a second lead.

- Once the leads are positioned correctly, they could be simply brought through the skin, or anchored with a small anchor device under the skin and attached to an extension lead, which is then brought through the skin.
- The leads or lead extensions will be taped in place, then covered with a dressing and connected to the eCLS.
- After surgery, the eCLS will be programmed to deliver therapy according to your needs.

5.2 Programming the External Closed-Loop Stimulator (eCLS)

- Your clinician will customize a program to fit your needs.
- Your eCLS can store up to four different programs, and you can access these programs using your EPC (refer to Section 7).
- Your eCLS may be required to be reprogrammed at any time during your trial period.

5.3 How it should feel

- Patients report that the feeling of using a stimulator ranges from nothing through to a tingling sensation.



Caution: If you feel any uncomfortable sensations, such as shocks, jolts, burning, pain or cramping around the chest or abdomen, use your EPC to adjust the level of stimulation (refer to Section 7).

- If your therapy remains uncomfortable, contact your clinician so they can reprogram your device to restore comfortable therapy for your pain relief.
- At the end of your trial stimulation period, your clinician will ask about the amount of pain relief you experienced with the Evoke System.
 - If you and your clinician agree that your pain relief was enough (usually greater than 50% reduction in pain scores), then you will be asked to consider getting a fully implanted Evoke System.
 - If you decide to get a fully implanted Evoke System, you can expect that the sensations you feel, and the amount of pain relief will be similar to the trial period.

5.4 Lead or lead extension removal and next steps

If you did not have lead extensions implanted:

- At the end of the trial stimulation period your leads will be removed.
- The dressings and any tape or sutures will be removed.
- The leads will then be withdrawn.
- This is a brief procedure and you should not feel any pain.

- The wound will then be dressed to allow healing.
- If you decide to get an implanted Evoke System, the leads will be inserted at a similar location after your wounds from the trial have healed (see Section 6).

Note: You may notice some differences between stimulation during the trial and with the implanted stimulator, as the permanent leads may not be implanted in exactly the same place as the trial.

If you had a lead extension implanted and decide to get an implanted Evoke System:

- The lead extensions will be removed, but the leads will remain implanted and connected to your implanted stimulator (see Section 6).
- If your implant surgery is scheduled for a later date after the trial period ends:
 - At the end of the trial, the lead extension will be cut and remain under the skin in your back and the leads will remain implanted in the same place.
 - The wound will then be dressed to allow healing.
 - When you receive the fully implantable system, the remaining cut lead extensions will be removed and the leads that remained implanted after the trial will be connected to your implanted stimulator (see Section 6).

If you had a lead extension implanted and decide not to get an implanted Evoke System:

- The leads, anchors and lead extensions will be removed.
- The wound will then be closed and dressed to allow healing.

5.5 The eCLS



Figure 5.1: The eCLS case. Your clinician will connect the eCLS to leads or lead extensions inside the eCLS case. Do not open the eCLS case.

5.5.1 Using the eCLS

The trial leads or lead extensions are connected to lead adapters and the lead adapters are connected to the eCLS by your clinician. Your clinician will then place the eCLS inside the eCLS case (see Figure 5.1). During the trial stimulation period, you may wear the eCLS, in its case, in a

pouch (see Section 9) or taped to your back. The eCLS and leads or extensions remain connected during the trial period. If the leads or extensions become disconnected from the eCLS, or you need to disconnect the eCLS for any reason, please contact your clinic.

 **Caution:** Do not open the eCLS case. If your eCLS case opens please contact your clinical team (refer to Section 5.5.4.2 Reconnecting the eCLS). If you have any issues with the eCLS during your trial stimulation period, please contact your clinical team.

5.5.2 eCLS battery

The battery in the eCLS is rechargeable and/or replaceable. It will be provided to you fully charged and should last the duration of your trial. If your eCLS battery is depleted during your trial, you must return to your clinic to have the eCLS battery replaced or recharged.



The 'Stimulator Battery' indicator on the EPC (see Section 7) will show a single orange bar when it is time to recharge the eCLS (see Section 8).

5.5.3 Stopping stimulation

There are two ways to stop therapy:

5.5.3.1 Using the EPC

1. Unlock the EPC by pressing  .
2. Press   to stop the therapy, or

5.5.3.2 Using a magnet

1. Hold the provided magnet over the eCLS for 2-3 seconds until you feel stimulation stop.

Note: If you have misplaced the supplied magnet, please contact your clinician.

5.5.4 Do not open the eCLS case

Do not open the eCLS case or remove the eCLS from the case during your trial stimulation period. Doing so could cause your leads or lead extensions to be pulled on, which may cause the leads to move and your therapy to change.

If the eCLS case is opened, the leads become disconnected from the eCLS, or you need to disconnect the eCLS for any reason, please contact your clinic.

 **Caution:** Saluda Medical does not recommend that you attempt to disconnect or reconnect your eCLS without assistance.

 **Caution:** Please follow the advice of your clinical team. If you wish to disconnect or reconnect your eCLS, only do so with assistance from a care-giver following the

instructions below. Do not pull on the leads or extensions or apply tension between the eCLS and the leads.

5.5.4.1 Disconnecting the eCLS

If you require the eCLS to be disconnected from the lead adapters, a care-giver should:

1. Turn stimulation off (see Section 5.5.3).
2. Open the eCLS case by separating the tabs on the eCLS case.
3. Remove the eCLS from the case.
4. Remove the lead adapters from the eCLS (see Figure 5.2), noting the port that each lead adapter was removed from.
5. Secure the lead adapters to your back using adhesive tape to ensure they do not pull on the leads.

If the lead adapters have been removed, you should return to the clinic to have the components reconnected.



Caution: Do not remove the leads from the lead adapters. Do not pull on the leads or extensions or apply tension between the eCLS and the leads while the lead adapters are being disconnected from the eCLS.

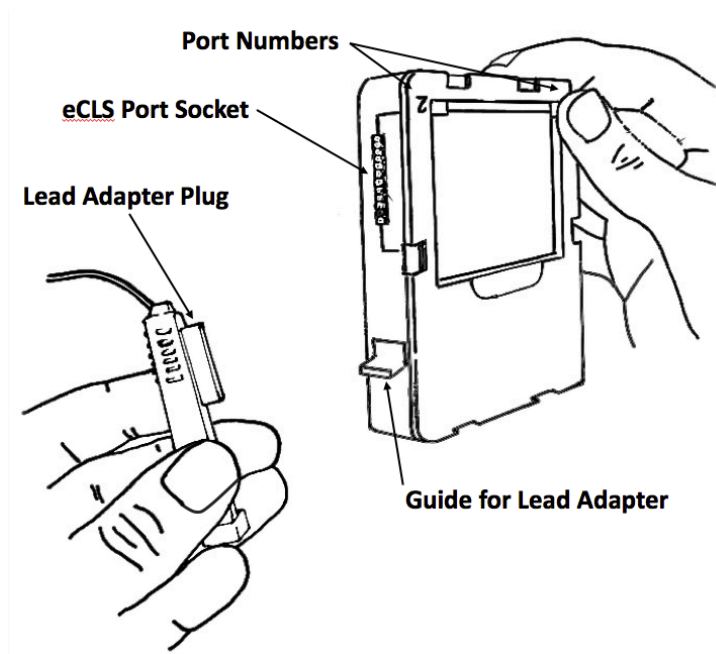


Figure 5.2: The Lead Adapter and eCLS. Port 2 of the eCLS is shown here. Port 1 is on the other side of the eCLS.

5.5.4.2 Reconnecting the eCLS

⚠ Caution: Saluda Medical does not recommend that you attempt to disconnect or reconnect your eCLS without assistance.

⚠ Caution: Please follow the advice of your clinical team. If you wish to disconnect or reconnect your eCLS, only do so with assistance from a care-giver following the instructions below. Do not pull on the leads or extensions or apply tension between the eCLS and the leads.

If you need to reconnect the lead adapters to the eCLS, please contact the clinic.

If your clinician instructs you to have a care-giver reconnect the components, they should:

1. Rest the lead adapter on the guide on the side of the eCLS and gently push the lead adapter plug into the socket on the eCLS port until it clips into place (see Figure 5.2).

Note: The eCLS ports are labelled “1” on one side for lead 1 and “2” on the other side for lead 2.

Note: Each lead adapter must be connected to the same port it was disconnected from. If you feel stimulation has changed after reconnecting the components, your leads may have been connected to the wrong eCLS port. If your stimulation has changed or you have any issues, contact your clinic.

2. To reconnect the second lead adapter, repeat step 1.
3. Open the eCLS case and orient it as shown below (see Figure 5.3), with the orange seal side on the left and the lead exits on the top.

4. Orient the eCLS (with lead adapters connected) so that the battery is facing up and the leads are exiting from the top.
5. Place the eCLS into the left side of the eCLS case (i.e. the orange seal side of the open eCLS case; see Figure 5.3).
6. Place the leads into the slots in the seal at the lead exits.

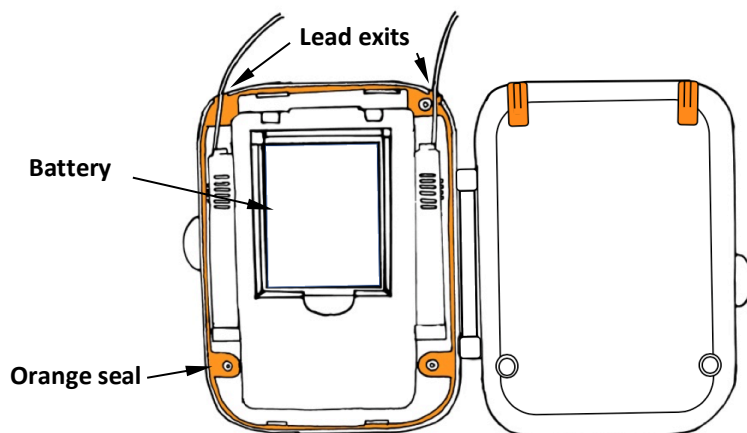


Figure 5.3: Place the eCLS with leads connected into the eCLS Case.

7. While taking care to keep the leads in the slots in the seal, close the eCLS case by folding the case shut until it snaps closed (see Figure 5.4).



Caution: The leads may be damaged when the case is closed if they are not in the slots in the seal at the lead exits. This could disrupt your trial stimulation.

8. Secure the eCLS comfortably to your back using adhesive tape or the Evoke Accessory Belt (See Section 9 'The Evoke Accessory Belt'). Avoid pulling on the leads or extensions, or applying tension between the eCLS and the leads or extensions.



Figure 5.4 eCLS with two leads connected enclosed in the eCLS case.

6 Fully implantable Evoke System

If you have a successful trial stimulation period, you and your doctor may decide to proceed to a fully implanted Evoke System, which includes the CLS, 12C leads, anchors, the EPC, and Charger. You should return your trial EPC and eCLS to your clinician.

6.1 Percutaneous lead and stimulator implant procedure

1. If your leads were removed at the end of the trial stimulation period, then new 12C percutaneous leads will be implanted in your spine by your clinician in a surgical procedure similar to the temporary trial stimulation procedure described in Section 5.1.
2. The leads will be secured to prevent movement.
3. The leads are then tunneled under the skin to the stimulator.
4. The leads will be connected to the CLS and the CLS will be placed 0.5 cm to 2.0 cm (0.2 in to 0.8 in) under the skin at the top of the buttocks, the flank, abdomen, or other site, as chosen by you and your doctor.

Note: You should tell your doctor on which side you would like the CLS to be implanted.

5. The incisions at the lead insertion site and at the stimulator site will be closed and covered with a dressing.

6.2 Programming

- After surgery, the CLS will be configured to deliver therapy according to your needs.
- Your clinician can store up to four different programs, customized to your needs, in your stimulator. You can access these programs using your EPC (refer to Section 7).
- Your stimulator may be re-programmed at any time if required.

6.3 How it should feel

- Patients report that the feeling of using a stimulator ranges from nothing through to a tingling sensation.



Caution: If you feel any uncomfortable sensations, such as shocks, jolts, burning, pain, or cramping around the chest or abdomen, use your EPC to adjust the level of stimulation (refer to Section 7).

- If your therapy remains uncomfortable, contact your clinician so they can reprogram your stimulator to restore comfortable therapy for your pain relief.

6.4 The CLS

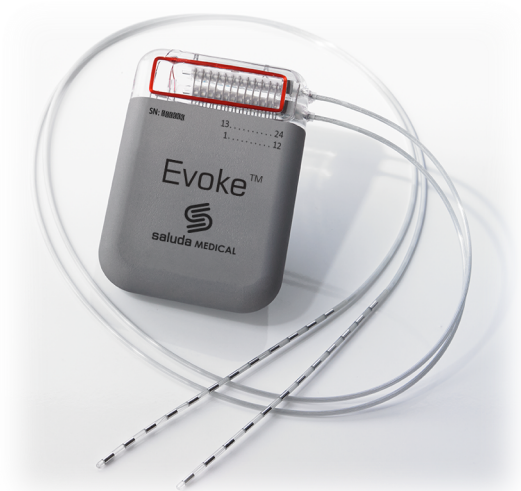


Figure 6.1: The CLS.

The CLS is a fully implanted version of the eCLS you used in the trial.

6.4.1 Controlling the CLS

Therapy delivered by the CLS can be controlled using your EPC. Refer to Section 7 for instructions on how to use the EPC.

6.4.2 Charging the CLS battery

The battery in the CLS needs to be recharged regularly in order to continue delivering therapy. Refer to Section 8 for instructions on how to charge the CLS using the Charger.

6.4.2.1 Battery Best Practices

You may prolong the life of your CLS battery by:

- Recharging it periodically, even if it is not fully discharged;
- Recharging it before it completely drains.

6.4.3 Stopping stimulation from the CLS

There are two ways to stop therapy:

6.4.3.1 Using the EPC:

1. Unlock the EPC by pressing  .
2. Press   to stop the therapy

6.4.3.2 Using a magnet:

1. Hold the provided magnet over the stimulator site for 2-3 seconds until you feel stimulation stop.

Note: If you have misplaced the supplied magnet, please contact your clinician.

Caution: Do not hold the magnet over the CLS for longer than 10 seconds or the CLS will shut down. When the CLS is shut down, the EPC will not control the CLS. To restart the CLS you must start charging (see Section 8). Once charging has started you will be able to control the CLS with the EPC again (see Section 7).

7 The Evoke Patient Controller (EPC)



Figure 7.1: The EPC to control your stimulator (CLS or eCLS).

The EPC is for controlling your therapy. During the temporary trial stimulation period, it controls the eCLS. After you receive a permanent implant, it controls the CLS.

Your clinician will create up to four different therapy programs (refer to Section 6.2) that you

can toggle between using the **PROG**  button. Each program is customized to your needs.

7.1 EPC buttons and indicators

EPC Lock/Unlock button



The 'EPC Lock/Unlock' button turns the EPC on and off. Turn the EPC off to lock the buttons from being able to change your therapy.

Turn the EPC on to unlock the buttons and see indicators. This enables you to stop stimulation, change programs, turn stimulation on, change therapy intensity, and check CLS and EPC battery levels.

Note: When you turn the EPC on, all of the lights will flash briefly. This is normal; you should only pay attention to the lights that remain on.

Note: The EPC will turn off and lock automatically after 2 minutes; this does not cause the stimulator to turn off.

Stop button



Press the 'Stop' button to stop therapy immediately. After turning stimulation off, you can start therapy again by

pressing .



Caution: You must unlock the EPC before you can use the 'Stop' button.

Increase Therapy and Decrease Therapy buttons

You can increase your therapy, from off to a comfortable level, using the 'Increase Therapy' button.



When you press the 'Increase Therapy' button to start stimulation, it will ramp up to the last level it was set to (the level indicated by the 'Therapy intensity' indicator light).



You can decrease your therapy using the 'Decrease Therapy' button.



Caution: You must unlock the EPC before you can use the 'Increase Therapy' and 'Decrease Therapy' buttons.



The 'Therapy Intensity' indicators will glow to reflect the level of your current therapy settings.

You can change the level using the 'Increase Therapy' and 'Decrease Therapy' buttons.

The number of glowing bars may not change with every click of the button, although the level of therapy will change.

When you have reached the maximum level for the current program, all seven bars will be glowing. When therapy is off, only one bar will glow and that bar indicates the level that you will start at when you press the 'Increase Therapy' button.

Change Program button



Use the 'Change Program' button to switch between up to four different therapy programs stored in your stimulator. One of the 'Selected Program' indicators will glow to show the program you have selected.

1. Press the 'Change Program' button once and the 'Selected Program' indicator will start flashing.
2. Press the 'Change Program' button again until the desired program is selected.
3. After 2 seconds, the 'Selected Program' indicator will stop flashing, stimulation will turn off, and the stimulator will change to the new program.
4. Start therapy again using the  button

 **Caution:** You must unlock the EPC before you can use the 'Change Program' button.

Stimulator Battery Level indicator



The 'Stimulator Battery Level' indicator shows the battery level in the stimulator, with three green bars indicating a full charge.



 **Caution:** When the orange bar appears, the battery level is low and should be recharged right away or therapy may stop soon.

EPC Low Battery indicator

When the 'EPC Low Battery' indicator glows orange, it indicates that the EPC battery is low. You should replace the batteries at your earliest convenience (see Section 7.3).



Caution: If you do not change the batteries, they will discharge completely, and you will not be able to use the EPC to make changes to your therapy.

Note: You can stop your therapy without the EPC by placing the provided magnet over the implanted Evoke CLS or the eCLS.

Contact Clinician indicator

The 'Contact Clinician' indicator will glow orange if the stimulator has detected a problem that may require you to visit your clinician for assessment.

Note: The 'Contact Clinician' indicator will not contact the clinician on your behalf. It is a message to inform you that you should contact your clinician.

7.2 EPC audio indicators

In addition to the visual indicators on the front of the EPC, the EPC will beep to indicate various functions:

- A short beep will occur every time you press a button.
- A long beep means your EPC has successfully communicated its command to the Evoke CLS or eCLS and a change has been made.
- Two beeps indicates that the Evoke CLS or Evoke eCLS has reached a limit and did not accept the request.
 - This will occur if you are at 1 (bottom) 'Therapy Intensity' indicator light and have tried to decrease the therapy.
 - This will occur if you are at 7 (top) 'Therapy Intensity' indicator lights and have tried to increase the therapy.
 - If you think your stimulator needs to be reprogrammed, contact your clinician.
- Three beeps indicates that the Evoke CLS or Evoke eCLS did not receive the request and a change was not made.
 - Move the EPC closer to the CLS or eCLS and try again.
- Six long beeps indicate that EPC batteries are running low and should be replaced.

- Ten long beeps, followed by the EPC switching off, indicates that the CLS has gone into Safe Mode, and you should contact your clinician, or that the eCLS battery needs recharging.

7.2.1 Switching audio indicators on and off

Follow the steps below to turn off Audio indicators:

1. Turn the EPC off (if it is not already off).
2. Press and hold the  button (until you complete the next step).
3. Press and hold the   button until the EPC turns on.

Note: When the audio indicators are off you will have no indication when the stimulator has reached a limit (2 beeps), or when the stimulator did not receive the request (3 beeps). For more information, refer to Section 7.2.

Follow the steps below to turn audio indicators back on.

1. Turn the EPC off.
2. Press and hold the  button (until you complete the next step).
3. Press and hold the   button until the EPC turns on.

7.3 Changing the battery in your EPC

Two AAA alkaline batteries power the EPC.

To replace the batteries:

1. Slide open the back cover.
2. Remove the old batteries from the battery compartment and insert new ones. Make sure the battery terminals are placed in the orientation that is marked inside the battery compartment.
3. Replace the back cover.

8 The Evoke Charger



Figure 8.1: The Charger and Charger coil.

The Evoke Charger is used to charge the battery in your implanted CLS. The Charger coil is used to wirelessly transfer charge to the CLS battery.

8.1 Charger buttons and Indicators

Start Charging button



Press the 'Start Charging' button for more than 1 second after placing the coil over the implant to commence the charging cycle.

Charging Link indicator



The 'Charging Link' indicator shows the quality of the link between the Charger coil and the CLS.



No charging possible.
Charger will beep every second.



Marginal alignment.
Charging possible but may take longer.



Acceptable alignment for charging.
Charger will beep once if the coil alignment falls below this quality.



Ideal alignment for charging.

Note: To improve the quality of the link between the Charger coil and the Evoke CLS, move the coil closer to the implant.

Charger Battery Level indicator



The 'Charger Battery Level' indicator shows the battery level in the Charger.



Caution: As the Charger provides the charge for recharging the CLS battery, it is important to start the charging session with a full Charger battery.

If the charge falls to one bar, recharge the Charger.

Note: Always recharge the Charger at the end of each CLS charging session to ensure you start the next charging session with a full Charger.

CLS Battery Level indicator



The 'CLS Battery Level' indicator shows how much charge is left in the CLS.

Note: The 'CLS Battery Level' indicator should show four lit bars at the end of each charging session.



Caution: When the 'CLS Battery Level' indicator shows one bar you should recharge the CLS battery as soon as it is practical.

If you do not charge the CLS battery, the CLS will stop delivering therapy.

Contact Clinician indicator



The 'Contact Clinician' indicator will flash six times if the Charger detects a problem with itself or the CLS and requires your clinician's attention to resolve.

If the 'Contact Clinician' indicator flashes, you need to contact your clinician so that they can investigate further.

Note: The 'Contact Clinician' indicator will not contact the clinician on your behalf. It is a message to inform you that you should contact your clinician during regular business hours.

8.2 Charging your Evoke CLS using the Evoke Charger

Follow the steps below to recharge your stimulator:

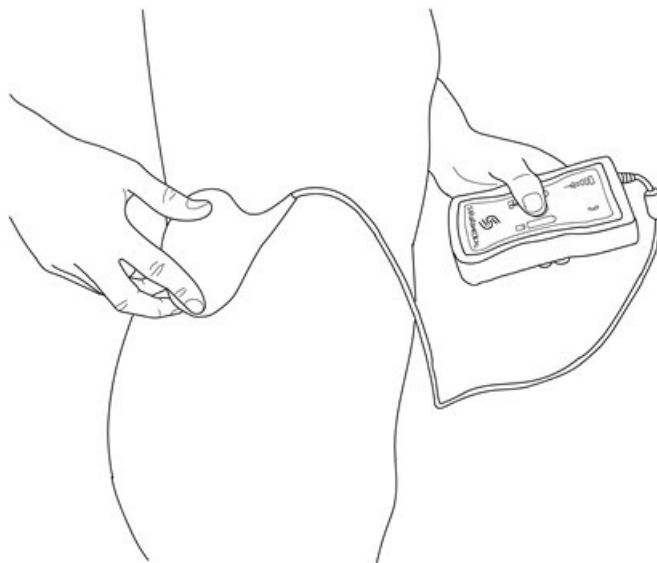


Figure 8.2: An example of positioning the Charger coil over the implant. Place Charger coil over clothing or in the Accessory Belt to ensure no prolonged contact with your skin.

Note: Your implant may be in a different location in your body.

1. Turn therapy off using the EPC (refer to Section 7).
2. Unplug the Charger from the power adapter.
3. Hold the Charger coil over the CLS (refer to Figure 8.2). You may place the Charger coil into the Accessory Belt pouch to hold the coil in place (see Section 9.2).
4. Place Charger coil over clothing or fabric to ensure no prolonged contact with your skin.
5. Press  for more than one second.
6. The Charger will beep every second until the coil starts to align with the CLS.
 - The 'Charging Link' indicator will then show at least two bars.
7. Move the Charger coil until the link is strongest. The 'Charging Link' indicator should then show three or four bars.
8. Keep the Charger coil in place over the CLS.
9. Do not wear the Charger coil on your skin for a prolonged time. Place clothing or the Accessory Belt between your skin and the Charger coil .
10. You may turn therapy on using the EPC once charging has started.

11. The Charger will beep once if the Charger coil moves out of charging range – realign the Charger coil so the ‘Charging Link’ indicator shows three or four bars.
12. When charging is complete, the Charger will emit a long beep (one second) and display four bars on the ‘CLS Battery Level’ indicator for 10 seconds.

 **Caution:** Turn therapy off before you start charging. You may experience increases or decreases in therapy strength if you start charging while therapy is on. You may turn therapy on once charging has started, however, closed-loop stimulation is disabled during charging and you may experience increases or decreases in therapy strength. In some cases, the therapy may stop during charging.

 **Caution:** When the orange bar on the ‘Stimulator Battery Level’ indicator on the EPC is displayed, you should charge the CLS or your stimulator will turn off and you will not receive therapy. If the stimulator turns off, you should charge the CLS as soon as possible.

Note: You must unlock the EPC before the ‘Stimulator Battery Level’ indicator illuminates.

8.3 Charger audio indicators

In addition to its visual indicators, the Charger will beep to indicate various functions:

- A short beep will occur every time you press a button.
- A long (one second) beep, accompanied by all the bars glowing on the ‘CLS Battery Level’ indicator for 10 seconds, indicates that the charge session is complete.
- A long (one second) beep where the battery level indicator does not illuminate, indicates that the charge session was aborted by the user.
- Three beeps indicates that the charge session has been aborted, and will be accompanied by a visual indicator of the reason why:
 - One bar glowing on the ‘Charger Battery Level’ indicator shows that Charger battery is too depleted to charge your CLS and requires recharging before use (refer to Section 8.4).
 - One orange bar glowing on the ‘Charger Link’ indicator for 10 seconds indicates a poor charge link.
- Three beeps accompanied by the ‘Contact Clinician’ indicator flashing on and off six times indicates an abnormal condition and that you should see your clinician to resolve the issue.

8.4 Recharging your Evoke Charger

Follow the steps below to charge your Evoke Charger:

1. If charging, remove the Charger coil from over the stimulator.

2. Plug the power adapter into a power outlet.



Caution: Be sure to plug the power adapter into a power outlet that is easy to access.

3. Connect the Charger to the power adapter.
4. The Charger battery level indicator will flash one to four bars every second while recharging the Charger.
5. When recharge is complete, the Charger will beep, and the 'Charger Battery Level' indicator will show four full bars (refer to Section 8.2 'Charger Battery Level indicator').



Caution: Do not leave the Charger power adapter plugged into a power outlet after recharging is complete.



Caution: You cannot recharge your Charger while you are using it to charge the stimulator. You must remove the power adapter from the Charger before using it to charge a stimulator.

9 The Evoke Accessory Belt

9.1 Wearing the eCLS with the Accessory Belt

During the trial stimulation period, you may wear an Accessory Belt to hold the eCLS. Place the eCLS into the Accessory belt using the following steps.

1. Place eCLS into the Accessory Belt pouch with the leads exiting the pouch at the top (Figure 9.1).
2. Close the pouch by pressing the Velcro sides together. The Velcro will fasten around the leads exiting the pouch.
3. Wrap the elasticated portion of the belt around your waist and attach its Velcro end to either the pouch or the belt itself. The belt should fit comfortably and securely around your waist.
4. Position the belt so that there is no pulling or tension between the eCLS and the leads.
5. To remove the Accessory Belt, hold the pouch and lift the Velcro on the elasticated belt to separate it from the pouch or belt.



Caution: To avoid pulling or tension between the eCLS and the leads, the belt should not be moved during the trial (see Section 5 'Temporary trial stimulation'). Please contact your clinician if you need to adjust the eCLS or belt.



Figure 9.1: Inserting the eCLS into the Accessory Belt.

9.2 Wearing the Charger Coil with the Accessory Belt

The Accessory Belt can be used to hold the Charger coil in position when you are charging your CLS. Follow the steps below to use the Accessory Belt with your Charger:

1. Place the Charger coil into pouch of Accessory Belt with cable exiting the pouch at the top (Figure 9.2).
2. Close the pouch by pressing the Velcro sides together. The Velcro will fasten around the cable or leads exiting the pouch.
3. Wrap the elasticated portion of the belt around your waist and attach its Velcro end to either the pouch or the belt itself. The belt should fit comfortably and securely around your waist.
4. Follow the Charger instructions (see Section 8.2) to charge the CLS.
5. Adjust the belt position if you need to re-align the Charge coil to the CLS.
6. When finished charging, remove the Accessory Belt by holding the pouch and lifting the Velcro on the elasticated belt to separate it from the pouch or belt.
7. The Accessory Belt is a re-usable item and may be machine washed at low temperature.



Figure 9.2: Inserting the Charger coil into the Accessory Belt.

10 Maintenance of EPC, Charger and eCLS

You can wipe the parts with a soft cloth dampened with water, alcohol or a mild detergent solution. **Do not use abrasive cleaners.**

Avoid wiping the connectors on the Charger and eCLS, if applicable.

DO NOT STERILIZE the eCLS, EPC or Charger. These items are supplied non-sterile. Sterilization could damage these components beyond repair and leave you unable to operate your stimulation system.

11 Disposal of devices

 **Caution:** Your eCLS, EPC and Charger contain batteries that could explode if they are placed into a fire.

These items must not be discarded in the normal municipal waste; please return to Saluda Medical for disposal via your clinical team.

12 Patient ID Card

Every CLS is supplied with a Patient ID card for the clinician to complete and give to you.

Keep this card some place safe, as you may need it to show to doctors or nurses who you see for other reasons, so they understand you have an SCS system implanted. You may also need to show security personnel in shops or airports if the implant triggers detectors.

Importantly, your Patient ID card will tell medical staff that you cannot have an MRI scan. If you move, change physician, or lose your card, contact your clinician for a replacement card.

13 Troubleshooting

If you are experiencing problems with your system refer to the suggestions below and contact your clinical team.

Table 13-1: Troubleshooting.

Issue	Resolution
 The 'Contact Clinician' indicator on my EPC or Charger is glowing	<p>The stimulator has detected a problem that requires you to visit your Clinician for assessment. Please contact your clinical team at your first opportunity and remember to take your EPC and Charger with you.</p> <p>Note: You will not be able to charge the stimulator if the 'Contact Clinician' indicator is flashing on your Charger.</p>
During charging, my Charger beeps continuously	<p>The Charger will beep once per second when there is a poor link between the Charger and the CLS.</p> <p>Reposition the Charger coil over the implant so that the 'Charging Link' indicator shows at least 2 bars .</p> <p>Note: Wait about 1 second between each reposition in order for the Charger to update the link.</p>
My Charger started beeping during charging	<p>The link between the Charger coil and your CLS has dropped below two bars so charging is no longer possible.</p> <p>Adjust the position of the coil until the 'Charging Link' indicator displays at least two bars as shown above.</p>
Charger will not turn on, or (during charging) beeped 3 times and turned off	<p>Press and hold the 'Start Charging' button  for 2 seconds. If nothing happens, or the Charger battery indicator is below 1 bar, plug the Charger into the power adapter (refer to Section 8 'The Evoke Charger').</p> <p>Once the Charger battery indicator is full, disconnect from the power adapter and try to charge again (refer  to Section 8 'The Evoke Charger').</p> 

Issue	Resolution
My EPC stimulation level indicator lights do not change when I increase or decrease stimulation	<p>Sometimes you will need to press the  or  button multiple times before the lights will change. This is normal. However, you should feel a change in stimulation intensity almost every button press.</p> <p>If you feel you need to be reprogrammed, please contact your clinical team.</p>
My therapy has stopped	<p>The stimulator will stop stimulation if it detects an issue or if the stimulator battery is too low.</p> <p>First try to restart your stimulator with your EPC. If the EPC does not connect to the stimulator, then refer to ‘Stimulator Battery too low’ below. If the EPC connects, but stimulation does not start, or it stops stimulation repeatedly, try the suggestions below.</p> <p>If you have an eCLS</p> <ol style="list-style-type: none"> 1. Stimulator battery too low: <ol style="list-style-type: none"> a. Please contact your clinical team to organize battery recharge or replacement. 2. Lead Disconnection: <ol style="list-style-type: none"> a. Do not open the eCLS Case. b. Please contact your clinical team. <p>If you have a fully implanted CLS</p> <ol style="list-style-type: none"> 1. Stimulator Battery too Low: <ol style="list-style-type: none"> a. Place the Charger coil over the CLS and press the ‘Start Charging’ button  for 2 seconds. b. If the CLS battery was low, allow it to recharge (refer to Section 8 ‘The Evoke Charger’), and restart stimulation (refer to Section 7 ‘The Evoke Patient Controller (EPC)’).
Stimulation strength becomes more variable	<p>This may happen during charging and should resolve once charging is finished.</p> <p>If this happens often when not charging, you should contact your Clinician to reprogram your stimulator.</p>

Issue	Resolution
Stimulation strength suddenly decreases	When the stimulation reaches some internal limits, it may decrease in strength automatically. You will be able to increase the strength again with your EPC. If this problem continues you may need to contact your Clinician to reprogram your stimulator.
The EPC will not turn on	The batteries that power the EPC may have run low. Refer to Section 7.3 'Changing the battery in your EPC', for instructions on how to replace the batteries in the EPC.
My EPC does not appear to be working	<p>If the stimulation is still on</p> <p>For help on performing any steps, refer to Section 7 'The Evoke Patient Controller (EPC)'.</p> <p>Ensure that the EPC is on when performing the steps below.</p> <ol style="list-style-type: none"> 1. Low battery: <ol style="list-style-type: none"> a. If the 'EPC low battery indicator' light is on you should change the batteries. 2. EPC not communicating with the stimulator: <ol style="list-style-type: none"> a. Turn on the audio indicators (if they are off). b. Try to use the EPC again, if you hear 2 or 3 beeps this means the command is not getting through to the stimulator. c. Bring the EPC closer to the stimulator and try again. If you have a CLS, bring the EPC to the side where the CLS is implanted, or try to hold it directly behind the implant site. <p>If the stimulation is off</p> <ol style="list-style-type: none"> 1. See 'My therapy has stopped'.
I cannot change programs	<p>To change programs, you will have to press the  button once (do not hold it) and then press it again while it is still flashing until you select your desired program. Refer to Section 7 'The Evoke Patient Controller (EPC)'.</p> <p>If your program light does not change from Program 1 then you have only been given one program; contact your clinical team if you think your stimulator needs to be reprogrammed.</p>

Issue	Resolution
Stimulation does not get stronger when you press the  button	When the stimulation reaches some internal limits, it will not increase. It may not show as 7 bars on the EPC. It may be fixed by changing posture or changing programs. If this continues you may need to contact your Clinician to reprogram your stimulator.

14 Package contents

Table 14-1: Package Contents.

Evoke Patient Controller (EPC) (Ref No: 3040)	1 x Evoke Patient Controller (EPC) 2 x AAA Batteries 1 x Magnet
Evoke Charger (Ref No: 3006)	1 x Evoke Charger 1 x Evoke Power Adapter
Evoke Accessory Belt (Ref No: 3039)	1 x Evoke Accessory Belt

15 Technical Specifications

15.1 Device Specifications

15.1.1 Evoke CLS

Table 15-1: 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 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 (recording only)	
Stimulation parameters	Current	0 mA – 50 mA (20 mA @750 Ω)
	Pulse Width	20 μs – 1000 μs
	Frequency	10 Hz – 1500 Hz

Radio frequency communication	MICS band	402.45-405.55 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)
	Range	1.0 m (3.3 ft.)
	Effective Isotropic Radiated Power (EIRP)	25 μ W (-16.02 dBm) maximum
	FCC ID	2AYGR-3002
*Channels are automatically selected when the communication session begins.		
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 μ s, frequency = 60 Hz, impedance = 750 Ω , 24hrs/day usage)*
*End of Battery Life is defined by Saluda Medical as the point at which the device can no longer maintain enough charge to provide 24 hours of therapy. At higher or lower settings, this defined end of life could be shorter or longer respectively.		
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 BYY” Where “SME” is Saluda Medical, “B” is the CLS model and YY is the two-digit year of manufacture	
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F) Max: 55 °C (131 °F)

15.1.2 Evoke eCLS (includes Case and Lead Adapters)

Table 15-2: Evoke eCLS.

Materials	eCLS body and case	ABS Plastic
	Case seal	TPE
Dimensions	100 mm x 85 mm x 20 mm (3.9 in x 3.4 in x 0.8 in)	

Weight	96 g (3.4 oz.)		
Electrodes	24	Port 1: electrodes 1-12, Port 2: electrodes 13-24	
Functional specifications	All other functional specifications are the same as the CLS (See Section 15.1.1)		
Radio frequency communication	MICS band	402.45-405.55 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)	
	Range	1.0 m (3.3 ft.)	
	Effective Isotropic Radiated Power (EIRP)	25 μW (-16.02 dBm) maximum	
	FCC ID	2AYGR-3036	
	*Channels are automatically selected when the communication session begins.		
Battery	800 mAh 3.6 V Li-ion rechargeable battery		
Charging	Li-Ion battery charger		
Ingress Protection eCLS in case	IP22 Rating for protection against access of solid objects greater than or equal to 12.5 mm, and for vertically dripping water when the device is tilted 15 degrees.		
eCLS	IP30 Rating for protection against solid objects greater than or equal to 2.5mm, and no protection against water.		
IEC 60601-1 / EN 60601-1 Classification	Type BF Applied Part Internally Powered Medical Electrical Equipment Continuous Operation		
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F)	Max: 55 °C (131 °F)
	Humidity:	Min: 0% RH	Max: 90% RH
	Pressure:	70 kPa (0.69 atm)	Max: 150kPa (1.48 atm)
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)

Table 15-3: Lead Adapter.

Materials	Body	ABS Plastic
------------------	------	-------------

Dimensions	55 x 13 x 13 mm (2.2 x 0.5 x 0.5 in)	
Lead connection	Ports	1
	12 spring connectors	Au plating on stainless steel
Lead Adapter to eCLS connection	12 pin plug	

15.1.3 Evoke 12C Percutaneous Lead (includes Trial Leads)

Table 15-4: Evoke 12C Percutaneous Lead (includes Trial Leads).

Materials	Lead body	Pellethane
	Lead ends	Pellethane
	Distal electrodes	Platinum Iridium
	Proximal connectors	Platinum Iridium
	Retention ring	MP35N ¹
	Conductors	35N LT 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	1.02 mm (0.040 in)
	Pitch	1.96 mm (0.077 in) center to center
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F) Max: 55 °C (131 °F)

¹ Alloy of Nickel, Cobalt, Chromium and Molybdenum. MP35N is not in contact with tissue but may be in contact with body fluid.

15.1.4 Evoke 12C Lead Extension

Table 15-5: Evoke Lead Extension.

Materials	Lead extension body	Pellethane
	Lead extension ends	Pellethane
	Proximal connectors	Platinum Iridium
	Retention ring	MP35N ¹

	Connector springs	Platinum Iridium
	Set screw	Titanium
	Header body	Silicone
Dimensions	Lengths	55 cm (1.8 ft.)
	Body Diameter	1.32 mm (0.05 in)
	Header Length	41 mm (1.62 in)
	Header Diameter	5.45 mm (0.21 in)
Connectors	Number	12
	Length	1.02 mm (0.040 in)
	Pitch	1.96 mm (0.077 in) center to center
Storage & Transportation Conditions	Temperature:	Min: -10 °C (14 °F) Max: 55 °C (131 °F)
¹ Alloy of Nickel, Cobalt, Chromium and Molybdenum. MP35N is not in contact with tissue but may be in contact with body fluid.		

15.1.5 Evoke Anchors

Table 15-6: Evoke Anchors.

Suture Anchor	Form	Two suture eyelets	
	Material	Silicone rubber	
	Diameter	5 mm (0.20 in)	
	Length	35 mm (1.38 in)	
Active Anchor	Form	Three suture eyelets, and a set screw to secure the lead	
	Materials	Body	Silicone rubber
		Set screw	Titanium
		Set Screw Block	Titanium
	Diameter	5.4 mm (0.21 in)	
	Length	35 mm (1.38 in)	

15.1.6 Evoke EPC

Table 15-7: Evoke EPC specifications.

Materials	Body and Battery Cover	ABS Plastic
	Buttons and Seal	TPE
	Lens	Polycarbonate

Dimensions	90.4 mm x 49.9 mm x 24.5 mm (3.55 in x 1.96 in x 0.96 in)		
Weight	73 g (2.56 oz)		
Radio frequency communication	MICS band	402.45-405.55 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)	
	Range	1.0 m (3.3 ft.)	
	Effective Isotropic Radiated Power (EIRP)		25 µW (-16.02 dBm) maximum
	FCC ID	2AYGR-3040	
*Channels are automatically selected when the communication session begins.			
Power Source	2 x AAA Alkaline batteries		
Battery Life	Approx. 60 days (dependent on usage)		
Expected Service Life	1 year		
Ingress Protection	IP22 Rating for protection against access of solid objects greater than or equal to 12.5 mm, and for vertically dripping water when the device is tilted 15 degrees.		
IEC 60601-1 / EN 60601-1 Classification	Type BF Applied Part Internally Powered 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
	Pressure:	70kPa (0.69 atm)	Max: 106kPa (1.05 atm)
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)

15.1.7 Evoke Charger

Table 15-8: Evoke Charger specifications.

Materials	Charger	ABS Plastic
	Control panel	PET
	Charger coil	Silicone

Dimensions	Charger	139.7 mm x 82.6 mm x 26.2 mm (5.50 in x 3.25 in x 1.03 in)	
	Charge coil	Cable length	60 cm (2 ft)
		Diameter	10 cm (3.9 in)
		Thickness	7 mm (0.28 in)
Weight	410 g (14.48 oz)		
Communication Link	Inductive coupling		
Battery	2 x 18650 Lithium ion protected cells		
Charging	Via the supplied power adapter		
Battery Life	5+ years		
Ingress Protection	IP22 Rating for protection against access of solid objects greater than or equal to 12.5 mm, and for vertically dripping water when the device is tilted 15 degrees.		
IEC 60601-1 / EN 60601-1 Classification	Type BF Applied Part Internally Powered 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
	Pressure:	70kPa (0.69 atm)	Max: 106kPa (1.05 atm)
Operating Conditions	Temperature:	Min: 5 °C (41 °F)	Max: 30 °C (86 °F)
	Humidity:	Min: 15% RH	Max: 90% RH
	Pressure:	70 kPa (0.69 atm)	Max: 106 kPa (1.05 atm)
Supplied Power Adapter Rating	Input Voltage	100-240 Vac, Class II Medical Electrical Equipment	
	Input Current	Max 0.3 A	
	Frequency	50 - 60 Hz	
	Output Voltage	8.4 Vdc	
	Output Current	Max 1.3 A	
	Ingress Protection	IP22 Rating	

Note: The Charger is isolated from the mains via the supplied power adapter.

15.1.8 Evoke Accessory Belt

Table 15-9: Evoke Accessory Belt.

Materials	Belt	Elasticized poly/cotton
	Belt fastener	Hook and loop fastener
	Pouch front	Brushed poly/cotton

	Pouch back	Perforated nylon
	Pouch fastener	Hook and loop fastener
Dimensions	Belt	85 mm x 960 mm (3.3 in x 37.8 in) unstretched
	Pouch	140 mm x 270 mm (5.5 in x 10.6 in) unstretched
Storage Temperature Limitations	Low: -10 °C (14 °F) High: 55 °C (131 °F)	

15.2 Wireless Communication

15.2.1 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 EPC.

At the beginning of each communication session, the 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 EPC and the CLS/eCLS is typically 1 m (3.3 feet). If you experience issues with the wireless communication between the EPC and CLS/eCLS, try the following:

- Hold the EPC closer to the CLS/eCLS.
- Move away from other devices that may be causing interference (see Section 15.3).
- 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.

15.2.2 Wireless Security

The Evoke SCS System has a communication range of 1 m (3.3 feet). To enable the EPC to communicate with an eCLS or CLS, it must first be paired with that stimulator. The 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.

15.3 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.

15.3.1 Guidance and Manufacturer's Declarations

Table 15-10 Electromagnetic emissions.

The Evoke SCS System is intended for use in the electromagnetic environment specified below. The patient, doctor or any other user of the Evoke SCS System should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
Radiated disturbance, 30 MHz -6000 MHz CISPR 11 (EN 55011)	Group 1, Class B	The Evoke SCS System is unlikely to produce electromagnetic any interference with nearby electronic equipment.
Conducted Emissions 0.15 MHz - 30 MHz CISPR 11 (EN 55011)	Class B	The Evoke SCS System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable for the battery powered devices or device consuming less than 75 W from mains power outlet (Charger with power adapter)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable for the battery powered devices. Charger with power adapter complies with requirements of the standard	

Table 15-11 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 Charger power adapter requires continued operation during mains power interruptions, it is recommended that the 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. 10s; 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 15-12 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 cables, 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 the battery-powered devices.	The separation distance between an interfering RF transmitter and any Evoke SCS should be greater than 0.3 m and the maximum power from the RF transmitter should not exceed 2W or

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	28 V/m at a distance of 0.3 m.
Proximity fields from RF wireless communications equipment	Up to 28 V/m at 0.3m at specified frequencies (refer Table 9, IEC 60601-1-2)	Tested at up to 28 V/m, devices continued to function during test.	

15.4 Federal Communications Commission (FCC)

15.4.1 CLS, eCLS, 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.

15.4.2 Charger

This device complies with Part 18 of the FCC Rules.

15.4.3 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.

16 Glossary

Table 16-1: Glossary.

Term	Definition
Accessory Belt	An elastic belt with a pouch to hold an eCLS or a Charger coil.
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/eCLS Charger.
Closed-Loop (CL) Stimulation	Stimulation that is automatically adjusted in response to measurements from the spinal cord nerves (ECAP) to maintain stable therapy. This is also known as ECAP-controlled closed-loop stimulation.
Closed-Loop Stimulator (CLS)	An implantable pulse generator capable of ECAP-controlled closed-loop stimulation.
Electrode	An electrical contact that may be used to deliver stimulation current or to measure responses from spinal cord nerves.
Evoke Patient Controller (EPC)	A remote controller that allows the patient to adjust the therapy output from the CLS/eCLS.
Evoked Compound Action Potential (ECAP)	The electrical signal from multiple nerve fibers in response to an electrical stimulus pulse.
External Closed-Loop Simulator (eCLS)	The eCLS is a non-implantable device with the same functionalities as the CLS.
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 or lead extensions and the eCLS during the trial stimulation period.
Lead Extension	Insulated cable that is connected to a lead for temporary use during the trial stimulation period.
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.

17 Symbols

Table 17-1: Symbols.

Symbol	Definition
 www.saludamedical.com/manuals	Follow the instructions for use on this website: www.saludamedical.com/manuals
	Follow the instructions for use
REF	Catalogue number
SN	Serial number
LOT	Lot number
 YYYY-MM-DD	Use by date (YYYY = year, MM = month, DD = day)
	Caution
	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 – dispose of this product according to local regulations
	Type BF applied part
	Non-ionizing electromagnetic radiation
	Do not use if package is damaged
	MR Unsafe. Not safe to use with MR imaging.

IP22	<p>Ingress Protection Rating 22:</p> <ul style="list-style-type: none"> Protected against access of solid foreign objects greater than or equal to 12.5mm diameter. Protected against vertically dripping water when the device is tilted 15 degrees.
IP30	<p>Ingress Protection Rating 30:</p> <ul style="list-style-type: none"> Protected against solid objects greater than or equal to 2.5mm, and no protection against water.
	Class II Medical Electrical Equipment
	Power supply connection
	Serial Connection
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

18 Contact us

Most questions you have about your Evoke SCS System 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 email us at info@saludamedical.com.

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