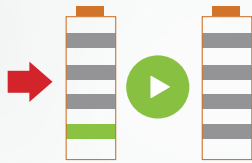


Charging the Charger

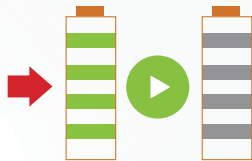
- 1 Plug power adapter into a power outlet and connect it to the charging unit.



- 2 The charger battery indicator on the Left Side will flash while the charging unit charges.



- 3 Charging is complete when the lights stop flashing and all 4 bars are green and the charging unit beeps.



- 4 Disconnect the charging unit from the power adapter. The charging unit is now ready to charge your stimulator.

Do not attempt to charge your stimulator while the charging unit is plugged into a power outlet

Important Safety Information

For U.S. — Consult product manuals prior to use.

Indications for Use:

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

Contraindications:

The Evoke System must not be used in patients who: Do not receive effective pain relief during trial stimulation, Are unable to operate the system, Are unsuitable surgical candidates.

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.

Warnings:

Sources of electromagnetic interference (e.g., diathermy, MRI, CT scans, electrosurgery, lithotripsy, external defibrillation, radiation therapy, ultrasonic scanning, highoutput ultrasound, TENS, psychotherapeutic procedures, laser procedures) can interact with the system, resulting in unexpected changes in stimulation, serious patient injury or death. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and electrical pulses from the neurostimulator may cause inappropriate response of the cardiac device. Allergic reaction to system components may occur. The Evoke System has not been tested for use in patients who are pregnant or nursing nor in patients under 18 years old.

Precautions:

Patients should avoid manipulating the Evoke System through the skin. Therapy should be discontinued immediately in the event of malfunction or failure of any component of the Evoke system.

Potential Risks:

Risks may include, but are not limited to epidural abscess, wound infection, lead breakage/fracture, lead migrations, IPG pocket pain, and muscle spasm or cramp.

Rx Only

EVOKE[®]
powered by  SmartLoop.

Saluda Medical Charger Quick Guide



 saluda MEDICAL[®]

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CLIN-MKT-010035 Rev 1.00

 saluda MEDICAL[®]

Saluda Medical Charger

Quick Guide

This Guide shows how to charge your implanted stimulator. It also shows how to adjust alignment to help charging take less time.

- ✔ Use your charging unit to help you recharge your implanted stimulator.



Before charging, turn on your Remote Control and **stop stimulation** by pressing the STOP button.



Scan to see a video about using your charger



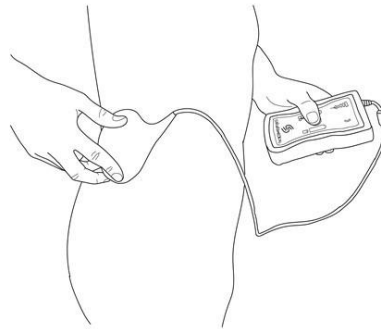
Please refer to your Evoke SCS System User Manual for detailed instructions on how to use your charger, and for detailed safety guidance, or contact your health care team.

Charging the Implant

- 1 **Disconnect charger from power adapter cord** when you are ready to charge your implanted stimulator.

Do not attempt to charge your stimulator while the charging unit is plugged into a power outlet

- 2 **Hold Charging Pad over implanted stimulator.**



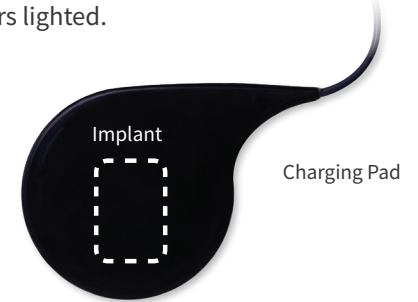
- 3 **Press and hold Green Button for 2 seconds.**



- 4 **Make sure the Charging Pad has a good connection with your implanted stimulator (2 green bars lighted).**



- 5 **If not,** move the Charging Pad in the area of your implanted stimulator until you see 1 or 2 green bars lighted.



- 6 **If the Charging Pad is not aligned within 30 seconds, you will hear 3 beeps and see orange bar glow on charging link indicator.**

Press the green button and try again to align Charging Pad.

- 7 Look at the **Right Side battery indicator** and see that your implanted stimulator is charged.



The charging unit will also beep once when charging is complete.

